Health Research Authority

HRA Latest, volume 6

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This newsletter provides updates on the wide range of projects we have already completed and those underway to streamline the research approvals process. It sets out the next steps we are taking to achieve our ambition to streamline ethics and NHS Research and Development approvals, to make it easier to do good quality research in the UK.

It is issued to coincide with the launch of a paper at the Lancet on increasing value and reducing waste in biomedical research regulation and management, which Janet Wisely has contributed to.

We announce new national booking and electronic submission services for Research Ethics Committee (REC) applications from Spring 2014, which will reduce complexity and inefficiency for researchers, who currently use three booking services and make paper submissions.

There is information about our new pilot for an application management and coordination service across the approvals system for complex studies.

We are setting out the HRA's expectations of research sponsors, as well as our plans for consulting on a new system that would allow them to publicly declare their suitability for sponsoring different types of research.

We also explain the latest milestone in the development of the EU Clinical Trials Regulation. The HRA has been supporting MHRA in the negotiations; we expect the regulations to come into effect in 2016.

Finally, we are including a link to an appearance by Janet Wisely on BBC 5 Live's Shelagh Fogarty programme in October, which has been kindly provided for us by the BBC.

HRA's record of continuous improvement

The HRA is fully committed to making it easier to do good quality research in the NHS. The improvements we have made to the National Research Ethics Service (now part of the Operations team at the HRA) have been widely recognised. Since the HRA was established we have been:

- Providing tools for researchers that clarify whether a project requires ethical approval by implementing two decision tools: 'Is it research?' and 'Does it need ethical review?'
- Increasing the transparency of health research by requiring the registration of UK trials in a publicly accessible database as a condition of favourable ethical approval from 30

September 2013.

- Improving Participant Information Sheets (consultation in use now closed, full launch early 2014).
- Improving both access to our guidance and awareness and understanding of our activities through a new website, newsletters, Twitter, and stakeholder forums.
- Reducing the average time for approvals by the Gene Therapy Advisory Committee (GTAC); since moving to the HRA, these have come down from 127 days (May 2011 – July 2012) to 52 days (September 2012 onwards).
- Streamlining the research pathway through making an Integrated Research Application System (IRAS) identifier which can be used across the research community to identify a study available when a project is created, and harmonising the checklists across IRAS partner organisations to help R&D staff.
- Simplifying approvals by removing the need for internal authorisations from NHS sites before submitting an application to a REC.
- A greater focus on patient and public involvement through a new strategy, underpinned by a series of surveys and workshops to understand the views of patients and the wider public.
- Taking over responsibility for the Confidentiality Advisory Group (CAG) - which advises on use of patient-confidential data for research and non-research purposes - from the National Information Governance Board; and reducing timelines for applications submitted to CAG
- Integrating The Overvolunteering Protection System (TOPS), which protects participants in phase I clinical trials, into the HRA, ensuring its UK-wide adoption.

Projects underway to improve the research process

HRA-led collaborative projects

The HRA is leading on a number of collaborative projects to improve the health research process, tackling areas highlighted as being inefficient currently. Together, these projects will help to streamline research.

i) Handling Amendments in Research

The review of amendments to research applications in the NHS can cause delays; a UK-wide model for handling them has been agreed, and plans for implementing it across the NHS are being finalised. In England, the HRA will provide the system for studies that are not processed through the NIHR Coordinated System for gaining NHS Permission (CSP).

ii) Improving the quality of applications

More than 1000 Research Ethics Committee (REC) applications could not be validated last

year (around 20% of all applications); feasibility work for the HRA Assessment and Approval (see also final article) confirmed that poor quality applications often came from inexperienced researchers. We have worked with the Association of Research Ethics Committees (AREC) to provide training to student applicants and supervisors. The HRA Operations team has developed and tested a standardised training session for delivery to local universities by HRA Regional Offices, and we are evaluating the training with a prospective review of applications from a sample of students. An area for students and other inexperienced researchers is being developed for the HRA website.

iii) Model contracts and agreements

The HRA recommends the use of existing standard model templates for health research contracts. The model agreement for non-commercial health research contracts is due for review and we have supported colleagues from Cancer Research UK and a number of universities who have worked together to identify areas for improvement. In late 2013 we appointed to a fixed-term secondment to progress the development of revisions to this and consult more widely.

iv) Streamlining pharmacy review of research

Having been working with the National Pharmacy Clinical Trials Advisory Group (NPCTAG) on a framework for a single technical pharmacy review of research involving medicinal products to remove duplication, the framework and toolkit are now complete and will be piloted in early 2014.

Related work in radiation approvals is also underway.

v) Standard Protocols

We are developing standard templates for protocols for different types of research, with a view to minimising variability in protocol quality and thus improving acceptability of applications for approvals, as well as improving the conduct of research. The work has started with clinical trials of investigational medicinal products, building on the international work in developing the SPIRIT guidelines. A draft template and associated guidance will be available for consultation in early 2014. Work on other study types will follow. In the longer term, improved protocol quality may allow a reduction in the number of questions included in IRAS.

More details on improvement and collaboration projects may be found at http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/improvements-to-the-research-process/

HRA projects

In addition to these collaborative projects, the HRA has been working on a number of initiatives that will help transform health research.

vi) Ethics Officer pilot

The pilot of the Ethics Officer function is a welcome additional service for applicants, providing them with advice on preparing for attendance at the REC meeting following submission of their application. In a recent HRA survey, 81% of pilot participants said they felt more prepared for a REC meeting, 58% were more able to answer questions, 88% found the advice given helpful and 80% found the support beneficial overall. This service will be rolled out in 2014.

vii) Proportionate Review

Proportionate Review – a more efficient approval process for applications with no material ethical issues – has proved a huge success, with more than 1000 studies already having received a favourable opinion through this route. Early positive results from a pilot with a reduced application dataset show that there is likely to be scope for further streamlining of Proportionate Review in 2014. A graph showing increased update of the proportionate review service and improved timelines is on our website.

viii) Research Governance Framework

When the HRA becomes a Non-Departmental Public Body (NDPB) in late 2014 (as a result of the government's Care Bill), we will take on responsibility for the Research Governance Framework. Ahead of this, we have initiated preparatory work to better understand issues with the current document. These projects will come together to create a revised framework, which we expect to be ready for full consultation when we achieve NDPB status.

New national booking service and electronic submission

The HRA's National Research Ethics Service will be launching a new national (UK-wide) booking service in Spring. This means that all bookings for applications to RECs will be made through a single phone number. Researchers will then be able to call the Central Booking Service to book in any application to a REC meeting, regardless of the type of study. The service will continue to offer the choice of the first available agenda slot in the UK or a slot at any suitable REC which may be geographically more convenient. For phase I trials, researchers may continue to book directly with the REC or use the new system. We continue to encourage researchers to discuss their application pre-booking with their local REC manager.

When the service is launched, all REC applications will also be submitted electronically from IRAS, reducing the burden for applicants in preparing paper submissions.

New pilot of application management and coordination for complex applications

We announce today a pilot of a new service that will manage and coordinate complex

applications for research approvals.

The HRA will recruit new staff to support researchers submitting applications that require review by a number of regulatory and review bodies. The staff will liaise between these bodies and help applicants negotiate the approvals process.

The service will also help us to better understand how sponsors and researchers navigate the approvals process, giving valuable insight for the HRA Assessment and Approval proposals (see also the final article in this newsletter). We expect it to reveal more about application quality, applicant preferences on timing of applications and identification of research sites, and the extent to which sites have been accurately identified at the time of REC application.

Alongside this service, we will increase the visibility of REC applications and correspondence in NHS R&D offices, so any issues arising between REC and R&D review processes can be addressed directly by relevant HRA or R&D staff. This is part of our commitment to improve integration between REC and R&D staff, and will provide a platform for closer working as part of the proposed HRA Assessment and Approval.

The new service of application management and coordination will be regionally piloted from Spring-Summer 2014.

HRA expectations of sponsors

The Research Governance Framework for Health & Social Care outlines the responsibilities sponsors have for the quality of conduct and delivery of research. The Concordat to Support Research Integrity (2012) seeks to provide a comprehensive national framework for good research conduct and its governance for Higher Education Institutions. Despite the presence of these and other documents aimed at supporting research integrity, concerns are still being raised by organisations that host and regulate research around the variability in:

- Understanding sponsors' responsibilities across all parties
- How sponsors address their responsibilities
- Transparency of what sponsorship entails – what researchers may expect of the sponsor and vice versa
- Understanding of which organisations are suitable to sponsor what type of research.

Whilst variability in these issues can present as problems in themselves, wider scoping of opinions and assessment of the broader issues has highlighted areas of concern, as well as identifying the problems these caused for sponsors, researchers and those responsible for regulation and governance. These include sponsors who have authorised applications either failing to describe the depth and outcome of scientific review of the project or failing to justify the approach to peer review when questioned by REC or R&D.

After an initial scoping exercise with sponsors and other stakeholders, HRA has published its Expectations of Sponsor Responsibilities and launched a consultation on a mechanism for sponsors to declare and promote their capacity to sponsor different types of research, simultaneously providing assurances to researchers and patient groups on their role. Full

details of the consultation can be found in the consultations and calls for good practice area of this website.

HRA Assessment and Approval – update

The proposals for HRA Assessment and Approval were approved by the HRA Board in September 2013 and have been welcomed by the Department of Health. The approval of the proposals is subject to consideration of affordability and the approval of the HRA business plan by the Department of Health.

These proposals would create a new integrated assessment conducted by qualified and trained staff, in which a favourable REC opinion would constitute HRA Approval to conduct research. This would allow R&D staff at NHS organisations to focus on setting up and delivering studies at research sites, based on local capacity and capability. Further information on these plans is available on the HRA website.

In the news

Clinical Trials report

The Medical Research Council's response to the Science and Technology Committee (Commons) report on Clinical Trials has been published. The HRA's response, published at the end of last year is available here.

Care.data

The NHS Information Centre is launching care.data, which is a database of primary care level patient data for research and non-research purposes. To support this, it is delivering leaflets to every UK household, offering patients the opportunity to opt out of providing data.

EU Clinical Trials Regulation

Informal agreement has been reached on the text of the European Clinical Trials Regulation; the HRA has been supporting the MHRA (the Medicines and Healthcare products Regulatory Agency), who have led for the UK during the negotiations. The text was endorsed by Member States on 20 December 2013 in the meeting of Coreper (Committee of permanent representatives of Member States). The text will go through linguistic and legal checks and then it will need to be formally adopted by both the Council of Ministers and the European Parliament before it can be published in the Official Journal of the European Union. Once the text is approved it is anticipated that it will apply from mid-2016; please check HRA and MHRA websites for further updates.

The links below give further information:

Consolidated text of the draft regulation as approved Committee of Permanent

Representatives (COREPER) on 20 December 2013: http://register.consilium.europa.eu/doc/srv?l=EN&t=PDF&gc=true&sc=false&f=ST%2017866%202013%20INIT&r=http%3A%2F%2Fregister.consilium.europa.eu%2Fpd%2Fen%2F13%2Fst17%2Fst17866.en13.pdf

EU Council Press Release: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/140241.pdf

European Commission Press Release : http://ec.europa.eu/commission_2010-2014/borg/docs/statement_20131220_en.pdf

EU Presidency Press Release: http://www.eu2013.lt/en/news/pressreleases/agreement-on-clinical-trials-major-step-towards-innovative-and-competitive-europe

Glenis Willmott, MEP Press Release: http://www.gleniswillmott.eu/

MHRA website: http://www.mhra.gov.uk

Call for good practice on identifying study participants

We have launched a call for good practice on models for identifying potential participants for research studies; the closing date is 31 January 2014. Whilst this focuses on the areas within our remit, we are hoping to find wider examples too. We will publish the outcome on www.hra.nhs.uk to enable the research community to benefit from the best ideas in the NHS.

How health research works

Before Christmas, Janet Wisely appeared on the Shelagh Fogarty programme on 5 Live to help explain how the health research process works. The BBC have now very kindly provided a podcast of this show for us.

Increasing value and reducing waste in biomedical research regulation and management

Janet Wisely, who contributed to this study, presented this paper on behalf of the team that wrote it, as part of a Lancet symposium on increasing value and reducing waste in health research on 8 January 2014. This is available at www.thelancet.com, and is available free by registering on the site.