Health Research Authority

HRA Latest, Volume 11

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HRA Approval programme update

Since the August update, development of the details of HRA Approval with stakeholders has progressed well and we are now undertaking a detailed planning phase for the roll out of HRA Approval. 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 this is an accurate reflection on current status where detailed planning and milestone setting have not been possible until we had funding and resource in place. We now have a team in place and are therefore in a position to proceed with some confidence on delivery. Our ambition is still to have HRA Approval available to all study types by December 2015.

Key decisions

- 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). This will be an IRAS form (not an HRA Approval form) as this enables UK-wide compatibility.
- Existing information systems (IRAS and HARP) will be developed to support HRA Approval and UK-wide systems. HARP is the internal information system launched successfully this year to support REC processes, ready for expansion to HRA Approval processes.
- 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 and controlled, with opportunities for learning and refinement during roll out.
- Assessors will be recruited into the HRA as a dedicated HRA resource. The expertise for technical assurances (such as pharmacy and radiation) will be coordinated by the HRA but provided by the NHS.

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Phased implementation of pharmacy assurances in HRA Approval

Pharmacy assurance will be a component of HRA Approval. The HRA is currently working with Cancer Research UK (CRUK), through the Experimental Cancer Medicine Centre (ECMC) network on the first phase of implementation. The HRA process coordinates one technical review for each study, which on completion provides an assurance to all the study sites. This reduces duplication in pharmacy review of new studies, as well as contributing to improved study set up times.

Between implementation in September and November 2014, twelve cancer trials have been reviewed by the Designated Pharmacy Reviewers, who are all pharmacy staff from the ECMCs, with more in progress. These reviews replaced the need for individual pharmacy departments to do over 50 of these reviews within the ECMC network alone.

Data analysis and quality assurance information will inform the phased implementation of the Pharmacy assurance, in a controlled way, ultimately extended to all study types requiring this type of review. For all studies the use of the materials and guidance on site set-up developed by the NIHR Clinical Research Network is strongly encouraged. These can be accessed through their website.

- CRUK press release, 8 October 2014

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Forthcoming vacancies

We will shortly be starting the next phase of recruitment linked to HRA Approval. These will be across a range of areas, to support the first phases of implementation of components of HRA Approval. Please keep an eye on NHS Jobs by searching 'HRA' for our vacancies.

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Transparency update

We intend to further update our requirements of sponsors in relation to the transparency of clinical trials. From 1 April 2015, the REC sponsor declaration will confirm that all clinical trials in active recruitment in the UK have been registered, including those that were approved before September 2013, i.e. before it was a specific condition of the REC opinion.

From 30 September 2014 sponsors are confirming in IRAS that all studies reviewed in the previous year have been registered or a deferral agreed.

We have noted the concerns highlighted by some researchers around the EU Clinical Trials Regulation, which is currently scheduled to be implemented in 2016, particularly around the details of Commercially Confidential Information (CCI). As a result, we have stated that the registration requirement deferral request option will remain until the introduction of the EU Clinical Trial Regulation.

Our Chair, Jonathan Montgomery, recently presented on transparency at a meeting of the 20th National Ethics Councils (NEC) Forum – the European Group on Ethics in Science and New Technologies (EGE) in Rome, 18-19 November 2014.

We appreciate that health research takes place in a global environment, and recently welcomed and

responded to the WHO public consultation on publication of clinical trials.

Replacement for the Research Governance Framework

Upon becoming a Non-Departmental Public Body (NDPB) on 1 January 2015, the HRA will take responsibility from the Department of Health for issuing guidance for research in England, in place of the current Research Governance Framework. The HRA has been working closely with the Devolved Administrations to fundamentally review the whole framework with the ambition to have a single, high level policy document setting out principles for good research across the UK.

The review of the framework included a number of projects which sought to explore areas of risk and good practice with comments sought from stakeholders across the UK. Most of the projects have now finished with the reports, and a summary of the comments received, available on the HRA website. The comment period for one related project, looking at consent for simple trials, is still open and any comments should be returned by **28 November 2014**.

The first Board meeting of the HRA as a Non-Departmental Public Body (NDPB) is scheduled to take place on Wednesday 21 January. An update on the new framework will be brought to this meeting with the intention for the framework to be published on the HRA website, and circulated to key stakeholders across the four nations for comment soon afterwards. A formal consultation period will follow later in 2015.

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Protocol guidance and templates

Working with researchers, sponsors and the EQUATOR team, we are developing templates and guidance for different study types. The templates will be particularly valuable to new researchers, but the main aim is to provide clarity about the information that reviewers need to assess research projects, and that research teams need to conduct the project effectively. The HRA templates will not be mandatory, but in due course applicants who use the template will have fewer questions to complete in IRAS. A protocol which follows this template is less likely to be delayed during the review process because it will provide the necessary information needed by reviewers. A template for clinical trials of investigational medicinal products (CTIMPs) has been released for consultation in use which can be found here. To inform future guidance and templates, user feedback will be requested by email on completed protocols from all stakeholders, whether authors, reviewers or users. Informed by evaluation of this, protocol templates for other types of study will also be tested.

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Ebola – expedited REC review

As the Ebola epidemic continues in West Africa, the international community has been increasingly focused on research into vaccines and medication.

Over the past two months, there have been media stories about a trial for a vaccine here in the UK, for example in The Guardian.

The HRA organised an expedited review for this trial at a REC that has experience in reviewing vaccine studies. A further three studies have been reviewed through this process.

This is a concrete example of how the HRA can work in an agile way to expedite ethical review for

critical research for the greater good – helping to further the UK's reputation for health research.

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'One stop shop' for advice on regenerative medicine open for business

The MHRA's Innovation Office is the new portal for all regulatory queries concerning regenerative medicines, and is already handling enquiries. The "one stop shop" service provides a single point of access from the four regulators in the field, the Human Tissue Authority (HTA), the Human Fertilisation and Embryology Authority (HFEA), Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA), who will provide a co-ordinated single response service for free regulatory advice.

Any query relating to the regulation of regenerative medicines, including Advanced Therapeutic Medicinal Products (ATMPs) can be submitted to the MHRA's Innovation Office and will be answered by the relevant experts from the four regulatory bodies.

Individuals or companies who have regulatory questions concerning regenerative medicines and who are unsure which agency to direct their enquiry to, or have a query that impacts several regulators, should use the Innovation Office advice form.

Janet Wisely, CEO of the HRA commented:

"We fully support this initiative and look forward to working with colleagues to implement it. The HRA has an ambitious improvement programme and fully recognises the need to work effectively with others to fully benefit from investment in the HRA to make the UK a great place to do health research. Researchers have already benefited from our improvements to the Gene Therapy Advisory Committee and our new team of application managers can provide additional practical support to applicants which will complement well with this new development."

Please click here for further details of this new service, and here for our resources page on regenerative medicine.

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Live consultations and surveys– closing shortly

We have three live consultations and surveys, which close shortly.

1. We are looking for comments on proposed guidance on seeking consent in a proportionate manner from patients to take part in large-scale simple and efficient research trials within the NHS. **This is open until 28 November**.

2. We are finding out public attitudes towards the recruitment of participants in health research, including a special website to make it easier to respond. **This is open until 30 November**.

3. We have issued an online survey to Chief Investigators who have applied to a REC and/or the Confidentiality Advisory Group over the last year to gain a greater understanding of your views about our work. If you have received an invitation, we would be very grateful if you would spend 15 minutes to complete the survey, which **closes on 30 November.** If you have any questions, please contact gordon.harrison@nhs.net.

We would value your contributions and, especially with the work on public attitudes towards the recruitment of participants, would appreciate your support through your organisation's media and social media channels to encourage the widest possible engagement.

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Consistency in REC review

Research Ethics Committees (RECs) have, on occasion, been criticised for providing inconsistent ethical opinions (both within and between RECs).

This issue has been considered by the National Research Ethics Advisors' Panel (NREAP), whose discussions on this issue have resulted in the publication of *"Consistency in REC Review".* This work was led by the NREA Dr Mark Sheehan and based upon his companion academic paper "*Should the decisions of Research Ethics Committees be consistent?*" (Sheehan and Yusof [manuscript submitted for publication]).

This document sets out what is meant by "consistency", whether it can and should be achieved and puts forward practical suggestions to improve the consistency of REC decision-making.

These suggestions have been considered by the UK REC management operational group, who have accepted the recommendations outlined in the NREAP paper and have agreed to take these forward.

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Research summaries on HRA website

We have recently completed the migration of research summaries from our historic NRES website to the main HRA website.

Research summaries first began being published in 2008, using information extracted from the REC application form. As part of their migration to the HRA website, improvements have been made in the searchability of the database so that research summaries can now be located by keyword, research type and date.

While some legacy systems issues have meant that some research summaries remain unavailable, we are working to improve this database where possible.

Any sponsor/researcher wishing to update the information within their summary should contact the REC manager for their study.

The information on RECs and their meeting dates is the final section of the NRES site to be transferred across to www.hra.nhs.uk. When this work has been completed, we will be closing down www.nres.nhs.uk. This is likely to happen early in 2015.

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