Health Research Authority

HRA Latest Volume 15

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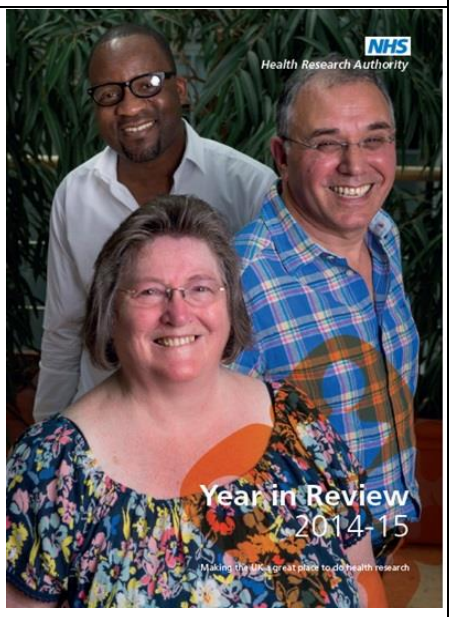
The Year in Review: How our work benefits the lives of patients



Today we are pleased to launch our new Year in Review, celebrating the successes of the previous year and looking forward to future activity.

In 2014/15 the HRA has continued its work to improve the environment for health research through our existing services and improvement programmes. We are delighted to share progress from the past year through the stories and experiences of those who we intend to benefit from our activities first hand – patients, the public and researchers.

We hope that this year's publication will be an enjoyable read as well as explain the different areas of our work and where we can add value to the health research landscape long term.

Year in Review highlights:

- **Listening to patients and the public –** read about our work with patients and the public to lead on the new UK wide policy framework to replace the Research Governance Framework and watch workshop videos on proportionate consent in large pragmatic trials
- **Transparency in research** – learn about our work with partners to promote transparency in research and continue to build public confidence in it
- **Making health research more efficient –** find out how the new pharmacy and radiation reviews have created efficiencies for researchers and pharmacists.

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HRA Approval:

Implementation continues in England

The phased roll out of HRA Approval began on 11 May 2015 for NHS staff research that does not require review by an NHS Research Ethics Committee.

For more information on how to apply please see:

- Applicant guidance
- NHS organisation guidance

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The next phase

We continue to roll out HRA Approval on schedule. The next type of studies to be eligible to apply for HRA Approval as part of the phased roll out will be those taking place in primary care independent contractor settings only. This phase will begin on 10 August 2015.

As part of this we will be introducing a new single IRAS form that replaces the current Research and Development and Research Ethics Committee forms for HRA Approval studies only.

More detail on this next phase of implementation can be found on the HRA website.

To assist General Practices we have released a factsheet outlining what HRA Approval will mean for them.

We are also actively seeking contact with sponsors and investigators whose primary care studies will be ready to roll out across the NHS from 10 August.

We continue to test the new Statement of Activities template as part of HRA Approval and are encouraging feedback on its use. The purpose of the new template is to enable participating NHS organisations to consider their capacity and capability.

The HRA will closely monitor studies going through the initial phases of HRA Approval roll out and will further develop processes as part of learning from and building on experience. Each roll out will build on the previous one. There will be changes to IRAS to accommodate future roll outs. The timing of the next roll out phase will be announced once the HRA has reviewed the implementation of the first two phases and we are confident we are ready to move on to the next phase as part of a controlled and quality assured release.

For more information on HRA Approval please contact us at hra.approvalprogramme@nhs.net

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REC Application Review and Advice service

The HRA has been developing and testing an extended Research Ethics Committee (REC) Application Review and Advice service. This new service aligns with HRA Approval as HRA staff help applicants during the ethical review process and will provide early benefit for studies that are in the later phases of HRA Approval roll out.

We aim to implement the service in a phased way over the next few months and therefore it will not come into effect for all studies immediately. We aim to provide the service to all studies submitted to England RECs by the end of the year.

The HRA has recognised that there is benefit in giving applicants to RECs the opportunity to provide clarification on any inconsistencies within the application or to provide any missing information in advance of the REC review. This means that the REC is able to undertake its review based on clearer, more complete and more accurate information. It also means that the applicant has the opportunity to gather information before the REC meeting, which is especially beneficial when the information is coming from different sources.

Feedback received so far has been very positive. Applicants have said that they found a lot of benefit in being able to provide information and clarification before the REC which has improved the experience. We have also noted an increase in the number of favourable opinions being issued as a first opinion which means that research is able to begin sooner. The work builds on earlier initiatives including the NRES ethics officer pilot and scientific officer approach in Scotland.

For more information please contact HRA Improvement and Liaison Manager Catherine Blewett.

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Seeking feedback on qualitative protocol guidance and template

The HRA is pleased to announce a consultation on the guidance and template to assist organisations and individuals to improve the consistency and quality of their qualitative protocols. We are requesting comments until 14 August 2015, when the feedback will be analysed and the guidance and template will be revised.

Our call for comment on the protocol guidance and template for use in a Clinical Trial of an Investigational Medicinal Product (CTIMP) closed in June 2015. We are now analysing feedback which will influence the final content of the document, which will be released later this year.

More information on the consultations can be found on our website here.

Feedback can be emailed to HRA.Protocols@nhs.net. Please contact us via this email address if you would prefer to provide feedback in person or by telephone and we can arrange a time to speak with you.

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Development of EU guidance for lay summaries of clinical trial results

The HRA has volunteered to lead on the development of EU guidelines for summaries of clinical trials results for lay persons. The summaries will sit on the future EU portal as part of the new Clinical Trials Regulations.

A cross-European taskforce has been established to oversee the development. This group includes both industry and patient representatives and is being chaired by Sir Nick Partridge.

A first draft of the guidance is expected in November 2015 and this will go out for a formal

consultation before the final presentation.

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Summary of responses – seeking consent for simple and efficient trials in the NHS

The HRA released draft guidance on seeking consent for simple and efficient trials in the NHS and we have now published a summary of the responses we received.

The need for this consultation arose because is not unusual to have a lack of clear evidence on the best treatment for a particular condition even where there are existing licensed treatments available. Often there is a lack of head to head trials with long term outcomes. Consequently there is a demand for further clinical trials to compare existing licensed products or those that are commonly used.

Given that a lot of information including data on safety and side effects from these treatments is already known, the HRA hypothesised that such Randomised Control Trials would involve lower risks to the participants as they would already be taking standard treatments.

With this in mind the HRA devised a set of scenarios for simplifying the consent process, and the amount of information that the potential participant could be provided with, on the basis that the trials would be unblinded and the participants would receive pack inserts about each drug.

The HRA's draft guidance on this topic included the scenarios for comment and the feedback to this can be found in the summary of responses.

We plan to issue future guidelines on this topic as part of a broader guidance on proportionate approaches to consent.

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Recruiting participants into health research

The HRA has been working with members of the public and patients to get a better understanding of their views on key topics which will inform our future policy and guidance.

To do this we commissioned research organisation OPM to run eight public dialogue workshops across England and Wales on the topic of recruiting participants into health research. The work was supported and part-funded by Sciencewise.

The public dialogue focused on three key areas:

- Who the public think can and should be allowed to access patient records for research (in order to tell them that they are eligible to take part in research).
- Different models for approaching potential research study participants; for example, allowing the public and patients to register their interests in advance so that researchers can make a direct approach to them should they be eligible to take part in a study.
- Simplified models of consent for large pragmatic clinical trials of already licensed drugs and other interventions in common use.

Members of the public debated these issues with patients and researchers and their views are being used to shape policy and guidance.

The final report is now available on the HRA website here.

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News from the NIHR: Clinical Research Network partnership to boost cancer research

The National Institute for Health Research's Clinical Research Network has announced a new partnership with Pfizer to further cancer research activity in England.

This model is already being used for work with Astra/Zeneca/NedImmune, GlaxoSmith Kline and Verastem. Read the full story on the NIHR website here.

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