Health Research Authority

# HRA Latest, Volume 12

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## The year ahead with Chief Executive Janet Wisely

December 2014 saw the 3rd anniversary of the Health Research Authority, although our history regarding research ethics can be counted back much further to NRES (National Research Ethics Service, 2007), COREC (Central Office for Research Ethics Committees, 2000-07), the first NHS REC meeting (1966) and a long standing history for ethics that purists would track back as far as Hippocrates in 500 BC.

The HRA gained important new functions and greater authority through clauses in the Care Act on 1 January 2015 when it was formally established as a Non-Departmental Public Body (NDPB). These extend the remit of the HRA to adult Social Care and it formally gains responsibility for health research policy from the Department of Health in England. The HRA has already started to scope roles for the new remit in social care and it will soon start to test the applicability of improvements in the NHS to the broader setting, and to identify new approaches for social care researchers. The HRA is hosting an initial 'by invitation' listening event for social care researchers on 24 February 2015. The change in status for the HRA will also see the transfer of the Social Care REC to the HRA from the Social Care Institute for Excellence (SCIE), and we would like to thank SCIE for their role in successfully setting up and hosting the Social Care REC in England.

The transfer of the policy functions to the HRA brings the policy and its practical operation for research in the NHS to one organisation in England. The HRA has a strong history of delivering sensible and pragmatic solutions to improve the environment for research. During 2015 the HRA will continue to build and extend its programme of work to make the UK a great place to do research. The first Board meeting of the NDPB will see it receive a draft of a new policy framework for the UK, which, with the agreement of our colleagues in Scotland, Wales and Northern Ireland, will be issued for comment and later consultation to enable the separate Research Governance Frameworks to be withdrawn in due course.

The HRA has a big agenda for health research, for a relatively small organisation, and key to our success is effective relationships with our stakeholders. By working together for the public, patients

and researchers to deliver our individual objectives we realise rewards, collectively, that are far greater than could be delivered in isolation. This cohesive approach is already producing benefits – for example, the roll out of a single pharmacy assurance, through the Experimental Cancer Medicine Centre network using pharmacists in the NHS through a system coordinated by the HRA. It is simple and efficient for researchers and releasing key front line resources to the NHS.

The HRA remains determined in its ambition to make it easier to do good quality research in the NHS. We will continue the long standing history of progress in improving the quality and consistency of ethics review and 2015 will see the controlled roll out of HRA Approval.

Transparency will continue to be a priority and the programme of activity to promote research transparency will continue as we look to extend registration requirements and set further standards for research findings. We expect the highest standards from researchers and research sponsors and like all public authorities it is important we live by those highest standards and corporate values ourselves, not least full transparency in all we do and engagement of all our stakeholders including patients and the public.

The HRA is proud of its achievements in three years and of our long standing history for research ethics. We would like to thank all within the organisation, including our volunteer members, and all those who have contributed to our success. We look forward to continuing to work with you in 2015.

*Janet Wisely, Chief Executive*

## Non-Executive Director Appointments

The HRA has made four Non-Executive Director Appointments; Mr Graham Clarke, Dr Allison Jeynes-Ellis, Professor Deirdre Kelly and Professor Nalin Thakker, who took up their posts on 1 January 2015 when the Health Research Authority was established as a Non-Departmental Public Body.

**Mr Graham Clarke's** career in life science R&D has predominantly been based in commercial organisations, including GE Healthcare, Amersham, GlaxoSmithKline, SmithKline Beecham, and with Deloitte and PA Consulting. He is currently CEO of a Cambridge-based immunology organisation, a member of the Institute of Cancer Research and a Trustee of the UK's leading children's cancer charity.

Graham has worked extensively within the complex landscape of multiple stakeholders, including patients, patient groups, medical schools, regulators, funding bodies and payers, in the UK and internationally. He views communication, alignment, streamlining and effective process management as critical elements for a successful UK research environment. With the HRA's new central role, Graham is passionate in ensuring that it delivers on its mandate of protecting and promoting patient and public interest through this exciting and demanding time.

**Dr Allison Jeynes-Ellis** returns for her second term with the HRA. She is a physician by background who, after working within the NHS, moved into the pharmaceutical industry. She is now the Chief Executive Officer of a start-up company which partners with other biotechnology or pharmaceutical companies to help them develop new medicines.

Allison is passionate about research from her days within the NHS treating patients with cancer at the Royal Marsden Hospital and helping to develop new medicines and changing the clinical research environment within the UK whilst Medical and Innovation Director at the ABPI. Allison is now looking forward to working with the HRA again as it continues work to streamline clinical research while

maintaining a patient-centred focus.

**Professor Deirdre Kelly** is Professor of Paediatric Hepatology at the University of Birmingham, Consultant Paediatric Hepatologist and Founding Director of the Liver Unit for Birmingham Children's Hospital NHS Foundation Trust.

Deirdre brings a strong background in health research with her to the HRA. She currently runs an active research programme focusing on viral hepatitis in children, molecular genetics of inherited liver disease, quality and outcome of life following liver and/or intestinal transplantation.

**Professor Nalin Thakker** is well known to the HRA and the research ethics community having served in various roles with NRES and the HRA over many years, including Vice Chair of a REC, National Research Ethics Advisor, and most recently as an HRA Advisor and member of the Health Research Authority-Human Tissue Authority liaison group. He is Professor of Molecular Pathology at the University of Manchester and Consultant Histopathologist at the Manchester Royal Infirmary. Nalin is also an Associate Vice-President of the University of Manchester and is responsible for a broad remit that includes all non-financial compliance & risk as well as research governance and integrity.

Nalin brings a very broad perspective and understanding of the research regulatory environment and its impact on patients, sponsors, and researchers. He is delighted to be working with the HRA in this new capacity to help deliver an outstanding environment for healthcare research in the UK.

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## Updated Approval Q&As

We regularly publish answers to questions that have been raised with us about the HRA Approval programme. The new edition of the Q&As is available on the HRA website. As the HRA Approval programme rolls out, we expect to receive further questions, so please return to the website for updates.

If you would like to raise a question please email us at hra.approvalprogramme@nhs.net

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## Operational job roles

The operational staff to deliver HRA assessment and Clinical Support assurance are being recruited to in phases over the coming months as HRA Approval is implemented in stages through 2015. All future opportunities will be advertised on the NHS Job site.

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## Preparing for implementation of HRA Approval

The HRA Approval Change Leads and Change Manager continue to meet with groups and individuals supporting the NHS and Local Clinical Research Networks across the country in their planning for change. It is expected that R&D offices and others supporting study set up and delivery will need to make adjustments to their office processes as HRA Approval is implemented in stages. There will be a time in which some studies are being processed through HRA Approval and others are processed using existing processes. When this time comes the HRA will give clarity on which studies are using which process.

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## Developing HRA assessment processes

The HRA is currently developing the standards and guidance against which the HRA will assess studies applying for HRA Approval alongside the REC review. In addition to this work we are also designing the processes for undertaking the assessment. The HRA is working with several sponsors to identify studies which we can use as a dry run through the process in order to support drafting of Standard Operating Procedures. These dry runs will continue for the next few months and will contribute to the further development and testing of the process and Standard Operating Procedures and to the training of staff.

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## Clinical support assurances

These components of HRA Approval continue to develop through early phase testing under the auspices of our partnership work with Cancer Research UK and the Experimental Cancer Medicines Centres (ECMCs). Workshops are planned for February and March with R&D staff and professionals from the disciplines to help trusts understand how these processes will affect current processes. These workshops are important for trusts to become ready for engaging with and getting the most out of coordinated assurances when these are applied across all relevant studies. For information on the workshops, please email n.pipe@nhs.net.

### i) Pharmacy Assurance

The initial implementation across early phase cancer studies continues well. By the end of December, 19 studies had been reviewed, achieving an estimated saving of 300 hours of pharmacist time across the Experimental Cancer Medicine Centres. Early Quality Assurance findings have enabled us to refine the review documentation to facilitate further consistency in reviews. Please email hra.pharmacyassurance@nhs.net for more information

### ii) Radiation Assurance

This component began in December, with a workshop of representatives drawn from multiple disciplines, including R&D, within the Experimental Cancer Medicine Centres Network. This month sees the next stage of the implementation phase as HRA accepts studies for review under the coordinated process. For more information, or guidance on the process, please email hra.radiationassurance@nhs.net.

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## Protocol templates and guidance

### i) Clinical Trial of an Investigational Medicinal Product (CTIMP)

The HRA consultation on use of the Clinical Trial of an Investigational Medicinal Product Protocol Guidance and Template with the research community is continuing. A multidisciplinary group of individuals from research-active organisations and regulators provided expertise to this project. The group has produced detailed guidance and a template in line with international SPIRIT guidelines. The guidance and template clearly define the expected components of a protocol and help ensure

researchers cover all the elements required by sponsors, Research Ethics Committees, the Medicines Healthcare Regulatory Authority (MHRA), and NHS sites. Comment and feedback is requested on the guidance and template by 31 May 2015 via email hra.protocols@nhs.net.

**ii) Qualitative Research- Call for expressions of interest in review of drafts**

The next phase of this project moves to studies other than clinical trials. Throughout 2015 a suite of protocol templates and guidance for research other than Clinical Trial of an Investigational Medicinal Product will commence testing, beginning with qualitative research. We value wide-ranging input and any individuals who wish to provide early feedback in the development of the protocol guidance and templates for qualitative methods should email hra.protocols@nhs.net to be included in a virtual workshop. Once you have contacted us draft documents will be sent to you requesting your feedback by 16 February 2015.

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## Feedback on revised model Non-Commercial Agreement (mNCA)

The original mNCA was released in 2008. It was intended to be used to agree the relationship between, and the responsibilities of, non-commercial sponsors and their research sites in relation to specific studies. The body of the agreement was written for use without modification, whereas the schedules could be tailored to reflect study specifics. Use of the template thereby ensured compliance with applicable UK law and institutional arrangements whilst minimising the review required at site.

Although the mNCA has achieved wide acceptance from NHS sites, a large number of non-commercial sponsors have retained their own templates and others have adopted the mNCA, but with modifications that require sites to undertake additional reviews. Against this background, the HRA has worked with a broad range of partners to revise and update the mNCA to ensure that the template reflects changes to the research landscape since 2008.

Comment is invited from all interested parties on the proposed new mNCA, particularly those responsible either for issuing agreements on behalf of non-commercial sponsors or for signing agreements for NHS research sites. These should be sent to the hra.mnca@nhs.net no later than Tuesday 3 February 2015.

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## Update on the Research Governance Framework

The HRA has been working closely with the Devolved Administrations over the past six months on a replacement for the Research Governance Framework. This has involved a fundamental review of the 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; we have published the reports and a summary of the comments received.

The new draft framework will be considered at the first meeting of the HRA Board as a Non-Departmental Public Body on Wednesday 21 January at Skipton House. Following this meeting the UK wide steering group responsible for the new framework will circulate it to stakeholders across the UK for comment and the document will be published on the HRA website.

An announcement regarding the comment period dates will be issued in due course. At the end of the comment period the HRA and Devolved Administrations will consider the feedback and revise the UK Policy framework as required - a summary of the comments received will also be produced. A formal consultation period will follow later in 2015.

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## NRES SOPs for Research Ethics Committees – version 6.1 published

The NRES Standard Operating Procedures (SOPs) for Research Ethics Committees have been revised and version 6.1 has now been published, along with a 'Summary of Changes' document outlining the changes from the previous version.

Comments and queries regarding the SOPs should be emailed to: nres.sop@nhs.net

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## NHS Research & Development Forum Annual Conference, May 2015, Manchester

This year's NHS R&D Forum Annual Conference will take place in association with the HRA on Tuesday 5 and Wednesday 6 May in Manchester. Over 400 R&D management staff and others involved with clinical research attend each year and it is considered the premier event for NHS R&D management in the UK. The HRA has worked with the R&D Forum to develop an integrated programme of updates, presentations and workshops. At the event, keynote speakers will aim to stimulate and challenge the audience and a series of workshops will share best practice and provide training opportunities. Networking is a key focus of the event and there will be a dinner attended by most delegates on the first evening.

Bookings for the conference are now open and details of speakers and workshops can be found on the newly launched, dedicated website. To book your place, visit the bookings section.

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