

## Press Release

31 March 2014

### **DH approves HRA business plan to deliver a single approval system for all health research studies in England**

The HRA welcomes the announcement of funding for our plans for HRA Assessment and Approval. This funding means that the HRA will be able to reduce duplication and bureaucracy by incorporating assessments by NHS staff alongside the independent Research Ethics Committee opinion, which will result in one application, one assessment and one approval for research in the NHS in England.

These proposals will build on recent improvements in timelines for approvals, will radically simplify the regulation of research and will remove complexity for researchers and industry.

#### **Case study – clinical trial**

Currently, a typical clinical trial can involve thousands of patients from more than 20 NHS sites, to ensure enough people participate. The research team will need to get the study reviewed by a Research Ethics Committee and also seek permission from each NHS organisation before they can begin to recruit participants there.

Researchers report that this process requires excessive effort and incurs unnecessary costs for all concerned, as well as causing delays to the overall research process and hampering the benefits of research for patients and the public.

The HRA will now streamline this complex process, with the HRA's Approval addressing practical, legal and ethical aspects of the study. This will allow local research teams to work with their NHS trust to set up and deliver the study.

The HRA will now be able to recruit a team to develop and implement the plans with key partners, particularly the NIHR Clinical Research Network. We will also work closely with the devolved administrations to maintain UK compatibility.

More details about the proposed arrangements and the timetable will be made available on the HRA website, [www.hra.nhs.uk](http://www.hra.nhs.uk), and in the HRA's regular newsletter.



Janet Wisely, Chief Executive of the HRA, said:

*'We are delighted that the Department of Health has approved our business plan. The research community will start to see further gains over the next few months. When fully implemented, this will streamline research in the UK: a real win for patients, for researchers, for funders and for industry, making the best value of everyone's contributions.'*

In announcing the funding, Earl Howe, Parliamentary Under Secretary of State for Quality, said:

*'I am pleased to announce the government will provide an additional investment of over £4.5m in 2014-15 to enable the HRA to take forward this important work.'*

Dr Jonathan Sheffield, Chief Executive of the National Institute for Health Research Clinical Research Network, said:

*'Clinical research is a vital component in improving treatments for NHS patients, so it is important that we do everything we can to streamline the process of setting up a study. That way, researchers can get to the business of answering the research question more quickly, and we can offer patients the opportunity to take part in studies that could benefit them without delays.'*

*'We look forward to working with the Health Research Authority as they develop their plans to implement the single approval system, building on the great work that we, and others, have already done to speed-up the process of setting up a clinical research study in the NHS.'*

Further details are available from: Gordon Harrison, Head of Communications, [gordon.harrison@nhs.net](mailto:gordon.harrison@nhs.net), 0207 972 2609

To arrange an interview during w/c 31 March with Janet Wisely, please contact Jamie Schneider, Website and Communications Officer, on [Jamie.schneider1@nhs.net](mailto:Jamie.schneider1@nhs.net), 0207 972 2688 or 07748 776644.

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### Further information

- The HRA protects and promotes the interests of patients and the public in health research
- A summary of the plan approved by the Department of Health is published at <http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/hra-assessment/>, along with further details.



- Researchers will benefit from HRA Assessment and Approval through the elimination of duplicate application routes and paperwork, enabling them to work on establishing research sites, recruiting participants and completing studies on time.
- Patients will benefit from Assessment and Approval through earlier opportunities to participate in studies and through more efficient and effective research leading to improved treatments and care.
- Industry will benefit from more joined-up access to NHS sites for research, making the UK a more attractive place for health research.
- Assessment and Approval will provide the platform for delivering the EU clinical trials regulations, ensuring the UK is ready and prepared and Industry can plan to place studies in the UK with continued confidence in UK readiness
- Assessment and Approval applies for all study types in England in the NHS.
- Health research falling under other specific legislation will still need approvals from other Regulators, these will continue to be coordinated within an overall UK wide framework for research in the UK
- To subscribe to the HRA's bimonthly newsletter, HRA Latest, visit <http://www.hra.nhs.uk/about-the-hra/our-publications/>

