Health Research Authority

HRA Latest, volume 5

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Stories

The HRA policy framework for supporting research in the NHS

The HRA has set out an ambition to make it easier to do good quality research in the NHS. A number of projects and initiatives that have been reported in previous editions of *HRA Latest* are already bringing practical improvements in the UK, and the HRA has presented business cases and an options appraisal to the Department of Health (DH) for HRA Assessment and Approval of research in the NHS. The DH has welcomed the proposals and supports them in principle. The HRA will continue to work through the financial arrangements and due process with the DH before a final decision can be made.

When the HRA becomes a Non-Departmental Public Body, which is expected in late 2014, it will take responsibility for the Research Governance Framework. Ahead of this, there is UK-wide agreement that the HRA begins to fundamentally review the principles on which the framework is based. This means that when the HRA becomes a NDPB, it will be ready to consult on a new document (having already consulted on changes that underpin the revision) to create a policy context to underpin the practical improvements that will deliver the ambition to makes it easier to do good quality research in the UK.

The clauses that will establish the HRA give the HRA specific duties. They also give others responsible for the regulation of research duties to collaborate with the HRA and for care providers in the NHS to pay due regard to HRA guidance.

Current position

The HRA has identified five key areas for exploration before we start drafting the new framework. These are:

- **Consideration of what research the NHS can and should support and how it can best do this.** The project will report early in the New Year and has been looking for evidence of where different types of studies may face particular difficulties. The survey is available here. Early indications are that the particular challenges are for student research, the quality of applications and the ability of some Universities to sponsor student research in the NHS. Through this project, the HRA is looking at alternative models for some student research and

how we can better support the educational value of doing research at an undergraduate level. This project is also looking at where local clinical protocols may be incompatible with a research protocol and how we align the different requirements, for example local variation in clinical protocols preventing research nurses delivering research within an approved research protocol. The project lead is Amanda Hunn, and the steering group for the project is Chaired by Professor John Saunders.

- **Gathering evidence to demonstrate the risk of research to research participants.** The HRA is mindful that the approach to the ethics and governance of research often starts with the view that research is a risky activity. This project is specifically gathering evidence of risk to participants, for example looking at reported breaches and misconduct from the perspective of risk to participants, and reviewing safety reports. This is an internal project being led by Catherine Blewett and Hugh Davies. The findings will be presented in May next year
- **Exploring how the perception that research raises risks to delivery of care, finance, resources and reputation for NHS organisations is a barrier to the delivery of research in the NHS.** This project, led by David Montgomery, is exploring these issues specifically with staff in the NHS and NIHR networks that have responsibilities for the governance and support of research in the NHS. The findings will be presented by April next year.
- **Exploring if Research Ethics Committee decision-making and operation present barriers to research.** This is an internal project pulling together the HRA data on approvals (and over 90% of applications to RECs do get approved); looking at practical hurdles in REC operation; setting out the legislation that may limit a policy approach as well as considering if there are other more effective research designs that are avoided because of this policy context. This will include the report from the HRA event in December on cluster randomisation. The report will be available next May.
- **Scoping the landscape for social care research UK-wide.** The HRA will take responsibility for social care research when it becomes a NDPB and one area which will need careful consideration is the different arrangements for social care research across the UK. This scoping project will start early in the New Year.

The re-write will also be informed by the public engagement work the HRA completed earlier this year and will have a dedicated public involvement workstream within the HRA public involvement strategy.

Next steps

These separate projects will be brought under a HRA policy work programme early in the New Year, with Steve Tebbutt as the programme manager. Key issues to consider will be:

- Scope – how much of the research journey do we cover in the new framework?
- Presentation of the framework - prescriptive or a set of principles?
- Will we bring GAfREC into the same document or keep it as a linked document?

The project team will meet for the first time early in January. The anticipated timing of key milestones is:

January 2014	Convene project team and advertise for policy lead to draft framework
Now – April 2014	Sub-projects and public involvement continue as discrete pieces of work
May 2014	Communicate and consult on findings from sub-projects

July 2014	Review and consider consultation findings and issue recommendations
October / November 2014	Issue and consult on new framework

R&D Forum 2014 – in association with HRA

We are pleased to announce that we are working together with the NHS R&D Forum team to deliver the 2014 Annual Forum, on 9-10 June in Birmingham. In February 2013, the HRA held a separate event. By combining the two in 2014, we can cover a wider range of topics together in a more integrated way in just two days.

Our plans are taking shape, but if you have any suggestions for topics you'd like us to cover, please email the conference chair, sarah.rickard@cmft.nhs.uk

AstraZeneca benefits from the joint HRA/NRES-HTA scheme for Research Tissue Banks

RTB status has created a single reference point for the ethical status of discovery projects without the need for multiple NRES submissions

The HRA's National Research Ethics Service has a long-standing agreement with the HTA to provide improved processes for the establishment of Research Tissue Banks (RTBs). Both organisations worked together to streamline the approval process where RECs can give ethical approval for RTB's arrangements for the collection, storage and release of tissue – when the bank's tissue is stored on HTA-licensed premises, and also allows for the approval of research projects to which the stored material can be assigned. The RTB scheme has now been running for 6 years and more than 200 banks are now jointly HTA-licensed and REC-approved. This has resulted in considerable efficiencies for patients, industry and academia.

AstraZeneca's site in Macclesfield, in the Northwest of England hosts the main oncology biobank and research site for AstraZeneca's global operations. Theirs was one of the first organisations to seek RTB status for its tissue collection early in 2007. RTB approvals are given for a period of 5 years and their bank received a 5-year renewal in 2012.

The bank holds approximately 170,000 samples – mostly tissue blocks and fluids such as plasma and serum – most of which are collected from clinical trials. Other samples are accessed through collaborations with many different groups worldwide based in hospitals and universities, and also with commercial organisations with whom they have third party agreements. Some of the samples are transported to colleagues at AstraZeneca in the USA and China, or to collaborators worldwide for testing.

Douglas McKechnie, Biobank Operations Manager, explained how the scheme worked within the Biobank Team and the benefits it has provided.

What difference did the RTB approval make to you? What impact has it had on your operations?

"It's far simpler and quicker for scientists to gain access to tissue samples and thus get on and do their research. Last year we had 344 requests to use samples from the biobank for about 100 different projects. Before the RTB scheme, each one of those 100 projects would have been subject to separate Ethics Committee Review or we would have had to have split the projects into research or therapy area themes. Either way, this would have been extremely time consuming not only for the Designated Individual, Biobank staff, and the scientists applying to RECs, but also for our legal team who must check each application. This efficiency has also had a positive financial impact on us too.

The scheme also benefits research participants. When the ethical approval for a clinical trial expires and if there is donor consent for future exploratory work to be performed on any left-over samples, we can utilise our RTB status to cover this work which means that we do not have to go back to individual participants to seek further consent, or to RECs for ethical review for each individual research project. Samples are now available for use more quickly, which means we can accelerate drug development work and ultimately bring treatments to patients faster.

"The RTB application was straightforward. It is so helpful to have one organisation rather than several RECs reviewing the application, and that the RECs have developed specialist knowledge relevant to biobanks. Now we have RTB status, AstraZeneca's internal processes ensure the rigorous scientific review of projects seeking to use human biological samples before an application reaches the Biobank. Final checks are then applied by the Biobank. The internal governance group reviews the biobanking activities annually and records any changes and new uses. A report is submitted to the HRA's Northwest Haydock Research Ethics Committee, one of several 'flagged' for tissue bank research.

Any other comments about the HTA's inspection and how the HRA and HTA support your work?

"Our HTA inspection was very constructive. We valued the positive interaction with the inspectors and the advice they provided.

"I read the HTA and HRA e-newsletters and discuss the highlights with the AstraZeneca Human Biological Samples user group who meet monthly so we all keep up-to-date with developments. The HTA's inspectors gave us positive feedback on how we share information in this group."

Patient involvement increases public confidence in health research studies

After a series of workshops and surveys coordinated and led by Amanda Hunn, we have now published our final reports, and issued a press release (below).

An Ipsos MORI survey of 1,295 British adults has shown that public confidence in health research studies can be increased by knowing that patients have advised on the design of the study.

Patient and public involvement in research has long been considered as an important element in ensuring more robust study designs, minimising dropout rates and leading to more meaningful patient outcomes. Health researchers are often encouraged to involve patients and the public in the design of their studies, but some researchers may not have understood this. They therefore may not have consistently communicated the benefits to potential participants in the recruitment process.

However, this survey, commissioned by the Health Research Authority (HRA), showed that More…

UK strategy for rare diseases

Following the Rare Diseases workshop in July to which the HRA contributed, the UK Strategy for Rare Diseases which was announced by Earl Howe on 21 November at Great Ormond Street Hospital and published on the 22 November. It is available on the GOV.UK website at:

Strategy:

https://www.gov.uk/government/publications/rare-diseases-strategy

Press release:

https://www.gov.uk/government/news/better-support-treatment-and-research-for-millions-of-patients-with-rare-diseases

Janet Wisely on BBC Radio 5

HRA CEO, Janet Wisely appeared with Lord Saatchi on the Shelagh Forgarty programme on 22 October 2013 to discuss clinical trials. Download the interview here (There are two separate files).

HRA response to Science and Technology Committee report on Clinical Trials

The HRA welcomed the publication of the House of Commons Science and Technology Committee report into Clinical Trials and the recognition of our role. We have already taken steps in the many of the areas identified by the Committee to improve awareness, promote transparency and improve efficiency in the regulation of health research in the UK.

This document provides the HRA's response to the recommendations. The government has also responded to the inquiry.