Health Research Authority

HRA Latest, Volume 14

Follow us on twitter for more HRA updates

Contents

Phased roll out of HRA Approval underway in England

The phased roll out of HRA Approval has begun with health services research studies involving NHS staff as participants that meet the following criteria:

- Identify participants by virtue of their employment status within a particular NHS service.
- Do not require review by an NHS Research Ethics Committee (REC).
- Take place in England only.
- Are not undertaken solely or primarily for educational purposes.
- The study is multi-site or single site (except where the single site is also the sponsor).

We have been actively seeking contact with sponsors and investigators since February 2015 in order to provide full support to initial applicants. To aid applicants and NHS organisations, new guidance is now available on the HRA website:

- Applicant guidance
- NHS organisation guidance

These studies will not require a Site-Specific Information Form to obtain NHS permission. We will be testing a new Statement of Activities template to be included as part of HRA Approval to enable participating NHS organisations to consider their capacity and capability.

The roll out of the next phase will be announced once the HRA has reviewed the implementation of the first phase. The HRA will closely monitor studies going through the first phase of the HRA Approval roll out and will develop processes further as part of learning from and building on this experience. Each roll out will build on the previous one. For more information on future phases, please see our cohort definitions document.

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

Back to top

Next steps for UK Policy Framework for Health and Social Care Research

The call for comments on the draft UK Policy Framework for Health and Social Care research closed on 1 May. This will ultimately replace the UK health departments' Research Governance Frameworks.

We received over 60 responses from key partners, national bodies, universities, NHS trusts, local authorities and individuals. Parallel exercises were conducted by the devolved administrations in Wales, Scotland and Northern Ireland.

Responses to the call for comments are now being analysed and a summary will be published following consideration by the steering group that oversees this work. The analysis of responses will feed into the further development of the policy framework and a revised version will be issued for formal public consultation later in 2015.

More information is available on the HRA website.

Back to top

HRA guidance on information for participants at the end of a study

We are now issuing new guidance for researchers on the information that should be provided to participants at the end of study. This follows extensive consultation with patients, researchers and industry.

The guidance applies to all clinical trials (excluding Phase 1 Healthy Volunteer studies) and other interventional or diagnostic studies and defines the end of a study from the participants' perspective - the study coming to a close for that participant.

The guidance suggests that participants should be thanked for their participation in a study and provided with the following information:

- What will happen to them at the end of a study, including arrangements for treatment
- How summary study findings can be accessed by participants
- How those who would rather not see the findings can opt out of this process.

The information provided in this end of study sheet should comply with the arrangements agreed in the original patient information sheet as agreed to by the REC and is not expected to require ethical review. However there are some instances when the end of study information sheet may require further ethical review and further details are given in the guidance below.

Researchers will be expected to include the end of study information sheet in their final report to the REC on completion of a study.

The guidance can be found on the HRA website here.

Back to top

Summary report: call for good examples of patient recruitment to health research

The HRA put a call out for evidence to identify good practice in identifying potential participants in health research. We asked for examples of different models for making information about research

available and identifying potential participants for health research studies. In this way, we are building on our remit to protect and promote the interests of patients and the public in health research.

We were particularly keen to hear about examples of patient and public engagement around models of recruitment and evidence on patient and public expectations relating to the identification of participants.

Thank you to all those who responded. The summary of the responses to our call can be found on the HRA website here.

This information will be used to inform and develop future HRA guidance on the identification and recruitment of potential participants in health research.

Back to top

Facilitating research into Ebola

We are pleased to announce that a further two clinical trials looking at the prevention and treatment of the Ebola virus have been given expedited review by the Research Ethics Service.

The Research Ethics Service has also continued to support the five previously approved clinical trials by reviewing urgent amendments to enable the studies to proceed.

This includes giving a decision in five hours for one urgent amendment that needed approval on the same day it was submitted.

This demonstrates again how responsive the UK Research Ethics Service is by enabling critical research to proceed in a timely way.

Find out more on these studies in our newly improved Research Summaries section of our website:

- Brincidofovir (CMX001) for Treatment of Ebola Virus Disease
- Evaluating Vaccines against Ebola
- A Phase I Study to Assess a New Ebola Vaccine, cAd3-EBO Z

Back to top

Confidentiality Advisory Group (CAG) precedent set review process

CAG's precedent set review process provides a transparent and timely review process for applications where advice which set a precedent has already been given by CAG in relation to the key issues in the application. A precedent set application received on the submission date can expect to receive advice from CAG within a maximum of 30 working days.

In order to ensure that the precedent set criteria remain valid and up to date, CAG carries out a review every six months. The latest version of the review was published in April and is now available on the HRA website.

To determine if an application is suitable, an applicant should first determine if it would fall within one of the criteria and should then consider whether any of the exclusion principles apply.

All applicants are advised to consult the criteria prior to submitting an application to ensure that the most timely review route is followed.

Back to top

Seeking feedback on HRA services

We routinely seek feedback from users of a range of HRA services including those using the REC service in the Devolved Administrations.

Gathering feedback from sponsors, REC and CAG applicants, chairs and members and HRA Staff helps us identify what we are doing well and areas for possible improvements.

We received some positive feedback over the October 2014 to March 2015 period:

- 94% of respondents rated REC/CAG staff either excellent or good
- 92% of respondents rated the HRA decision tools as either excellent or good
- 90% of respondents agreed that the HRA's online guidance was either excellent or good

When asked for comments on the service received, one respondent noted:

"Staff on the HRA queries line and the staff member I was in touch with at the REC office could not have been more helpful or efficient. I was so impressed and so appreciated their time and patience as I had never gone through this process before so had a number of queries and some amendments to make. The quick turnaround with a decision was excellent and gold standard".

We also act on feedback which indicates a need for service improvement. We were advised that some RECs were asking for information about which Research Tissue Banks were being used to source tissue. This detail should not be required by the RECs and we have now issued guidance to advise that this should not be requested. We also undertook significant work to rectify faults within the IRAS authorisations process in response to feedback on this system.

Read more in the full bi-annual User Satisfaction Report for October 2014 to March 2015.

If you have any feedback or comments please view more information on our website.

Back to top

New REC Directory on HRA website

The new REC Directory is now live on the HRA website here.

It enables users and researchers to search for RECs by region and committee types and find contact details for the REC they wish to apply to.

This new directory is replacing that on the old National Research Ethics Service (NRES) website.

The NRES site will close on 1 June, so please make sure you update any hyperlinks on your website or references in any other materials to direct people to the equivalent page on www.hra.nhs.uk.

If you have any feedback or comments on the new REC Directory, please email hra.comms@nhs.net

Back to top

Research-active trusts have better patient outcomes

A recent study showed that patients cared for in research-active acute NHS Trusts have better outcomes.

The results of the research, published in an international, peer-reviewed journal, demonstrated a direct association between higher levels of research-activity and lower rates of patient mortality following emergency admissions.

Read the full article on the NIHR website here.

Back to top

Please circulate this to your colleagues. Subscribe to HRA communications here and unsubscribe by email here.

Follow us on **twitter** for more HRA updates.