Health Research Authority

HRA Latest, Volume 13

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Strong public support for health research

A survey of over 1000 members of the public, commissioned by the HRA, shows that 97% of the public think health research is important and 74% think every patient should be offered the opportunity to participate in research.

These findings were backed up by other measures of public confidence and interest in health research; 65% were willing to participate in research themselves and 89% felt they would be treated with dignity and respect.

There was also a rise in public confidence in the benefits of the ethical review of health research, with confidence in studies reviewed by a REC reaching 82%.

In addition to surveying the public we sought the views of researchers and the volunteers who are Chairs and Vice Chairs of our Research Ethics Committees (RECs) and the Confidentiality Advisory Group (CAG). We did this to gain a rounded view of the organisation. The full report also includes strong indicators of support for the Health Research Authority and positive feedback on the work of its committees.

Researchers advocated public involvement, with 82% seeing it as important in their work.

They also believed that the registration of clinical trials (76%) and the publication of research summaries (73%) will both have an impact on public confidence in health research.

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Increase in public involvement in health research

The HRA and INVOLVE joint report- *Public involvement in research applications to the National Research Ethics Service: Comparative analysis of 2010 and 2012* data shows an 11 percent rise in public involvement over two years for non-commercially funded studies and a smaller increase within commercial research study applications of 3 percent.

The report forms part of a body of work carried out by the HRA and INVOLVE to encourage patient and public involvement within health research and makes a series of recommendations. These primarily focus on how Research Ethics Committees (RECs) and funders can help researchers understand what public involvement is, how it benefits health research and how it differs from engagement.

The HRA and INVOLVE will now focus on the recommendations made in the report and continue to analyse the pattern of responses on public involvement in applications for ethical approval. We will also provide further analysis of the data to assess the impact of public involvement on the initial decision taken by the REC and the time taken for the final decision to be made.

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Facilitating research into Ebola

The Ebola crisis has brought research ethics into the spotlight due to a requirement to be reactive to the need for medical treatment for a largely unprecedented epidemic which has threatened to become a global crisis.

We are pleased to announce that the HRA has successfully used well-established procedures for expedited review of research in such public health emergency situations to facilitate full ethical review of clinical trials looking at the prevention and treatment of the Ebola virus. Research Ethics Committees (RECs) have reviewed a total of five clinical trials and have issued a favorable ethical opinion in an average of five days. In one case the favourable ethical opinion was issued the day after the application was submitted to the REC for review.

This demonstrates how responsive the UK research ethics service is to such public health emergency situations to enable critical research to proceed in a timely way.

Our Research Ethics Adviser Hugh Davies has written a short article on Jenner's ground breaking research on smallpox vaccination, set in the context of this present-day work on Ebola.

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Opinion piece: How can Edward Jenner's experiment on James Phipps help us review today's research? By Hugh Davies, HRA Research Ethics Advisor

Since the recent Ebola epidemic, there's been controversy over the ethical standing of research into its treatment and prevention. One position starts with the proposition that research should carry no more than "minimal" risk and goes on to claim that, as therapeutic Ebola research carries more than this, it

must therefore be unethical. Others would disagree.

I'd suggest that Edward Jenner's "experiment" in 1795 when he "vaccinated" James Phipps is an historical analogy that might help and provide us with five questions to start review of research that might carry greater than minimal risk.

It's a common claim that Jenner exposed James to unacceptable risk. Conversations on this issue often end with the (grumpy) claim or conclusion *"It wouldn't be passed by an ethics committee today!"*

To start then, how might Jenner (if he'd had to) have presented his case (1)?

"Mr. Chairman, my work is designed to explore how we might prevent people contracting smallpox, a disease that kills or maims many when it strikes and for which our current method of prevention (variolation) still carries significant risk of death and disfigurement. We need a safer alternative and I believe cowpox, a disease in our countryside, may hold the answer. That is the purpose of my work, to test this idea. So when there is fear of smallpox coming to our town, I propose to collect fluid from a human cowpox vesicle and inject it into the skin of a suitable subject to determine if it then later provides protection against smallpox."

If we consider his likely arguments to seek the committee's favourable opinion we see an emerging set of questions.

Question 1. Given factual errors are very likely to lead to ethical errors.

What will happen? What may be withheld? An exact picture of research procedures is needed.

Question 2.

"We need a better means to prevent smallpox. We have no current treatments and the disease is often fatal."

What is the research purpose? Justifying risk requires justifying purpose.

Question 3. *"What might be the benefits? I hope you don't think I am being presumptuous but our deliberations and any decision must rest on all consequences of research. You must agree that a safe means to protect against smallpox would be of huge and undoubted benefit. Robust research is essential. The century long debate and hostility to variolation must surely teach us of this. It was finally numbers that answered counterarguments. At times I would argue that research is the only ethical way forward. We are, I argue, at such a point.*

What benefits might there be? When assessing the consequences of research, review must include assessment of possible benefits.

Question 4.

"I think it important for us to separate the (considerable) risk of smallpox which any subject of my work would carry anyway. This is NOT a research risk. Nor is my proposal to variolate any subject. This would happen anyway, it might be deemed "routine care". I provide variolation as I would normally but the research has it as its end point. Vaccination would have been successful if variolation doesn't "take". The risk of my work is therefore vaccination alone."

What are the separate risks? Risks of the disease, treatment and research procedures must be separated.

Question 5.

"I am not in what is termed a position of "equipoise". I, with fair reason, am not uncertain about the superiority of vaccination (and I can give you examples). I now feel that if I didn't offer vaccination I would be harming my patients in as much as I would be offering them inferior treatment."

In comparative studies is there equipoise or uncertainty as to which treatment is better?

Reference

1 Davies H 2007. Ethical reflections on Edward Jenner's experimental treatment. J Med Ethics;33:174-176 doi:10.1136/jme.2005.015339

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- **HRA Approval**

Implementation of HRA Approval – cohort definitions

Early in the HRA Approval programme, the HRA set out an intention to implement HRA Approval in a phased way during 2015 based on study types. We have tested and reviewed the order within the HRA and with stakeholders. A paper describing the current definitions of each of the cohorts is available on the HRA website. This will support stakeholders in their planning for HRA Approval implementation.

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Call to sponsors and funders for cohort 1 studies

The first cohort of HRA Approval roll out will consist of specific types of health services research in the NHS in England which are restricted to recruiting NHS staff. We would like to speak to sponsors and funders of this type of health services research to assist with:

- Identifying studies likely to be eligible for inclusion in the first cohort.
- Supporting researchers to understand the new process.
- Identify health services research studies opening before the first cohort that could be used by the HRA for dry runs through the process to test our internal procedures.

More information is available on the HRA website.

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New job opportunities

The recruitment of operational staff to deliver HRA assessment and clinical support assurance is underway and we have appointed the first group of staff. Future opportunities will be advertised on the NHS Job site over the next few months.

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Feedback on revised model Non-Commercial Agreement (mNCA)

The feedback period on the proposed new mNCA has now closed. We received over 50 responses and are collating the feedback with a view to updating the template. We will work with a range of NHS

and university stakeholders on the revised version to ensure it can be used from summer this year.

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Transparency: HRA updates requirements for sponsor registration of clinical trials

We are continuing to build upon our commitment to strengthen public confidence in health research by updating the HRA's requirements of sponsors relating to transparency in clinical trials.

From 1 April 2015 we will require sponsors to specifically declare that all clinical trials given a favourable opinion by a Research Ethics Committee (REC) within the UK Health Departments' Research Ethics Service since 30 September 2013, and those given a favourable opinion prior to this date and currently in active recruitment in the UK, have been registered on a publicly accessible register in compliance with HRA requirements or have agreement from the HRA for deferral of registration.

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- **New to the HRA website**

Phase 1 studies

We have developed a dedicated area of the HRA website in response to feedback from representatives of Contract Research Organisations undertaking early phase clinical trials. It provides information on Phase 1 clinical trials which we hope will be particularly helpful to organisations which sponsor or undertake this type of clinical trial.

The Phase 1 webpage includes information on the following:

- The HRA initiative to facilitate shorter and more predictable timelines for the review of Phase 1 clinical trials by allowing the option to submit applications up to seven days before the REC meeting.
- Information relating to the requirement to register clinical trials as a condition of the favourable ethical opinion.
- Information about The Over-volunteering Prevention System (TOPS). This is a system to identify when a potential participant registering for a Phase 1 clinical trial has recently been a participant in another clinical trial to ensure there is an appropriate gap between trials.
- Information about the Phase 1 Advisory Group and the minutes of previous meetings.
- Information about the Phase 1 Advert Review Committee and details of when and how non study specific Phase 1 adverts should be submitted to the Committee for review, as well as information about upcoming work looking at the review of non-study specific screening documents.
- General guidance relating to Phase 1 clinical trials.

We want to ensure that the information in this section is useful so we welcome feedback on existing content or suggestions for new content. All feedback should be sent to catherineblewett@nhs.net

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Confidentiality Advisory Group (CAG) resources and updated guidance

Sections of the HRA website relating to the CAG application process have been revised to provide

additional guidance and information about what to expect at each stage of the application process.

Review Process and Amendments

In particular potential and current applicants are advised to consult new guidance on the review process and submitting amendments. An amendment template has been established to clarify types of amendments that require further CAG review and the information needed to support this review.

Guidance on reducing the disclosure of confidential patient information

The HRA, in collaboration with the Medical Research Council, has also developed guidance on reducing the disclosure of confidential patient information for all applicants and potential applicants. This can be found on the CAG resources page of the HRA website. This guidance should be consulted by anyone thinking about submitting a new application to CAG or completing an annual review. CAG is required to consider whether the information requested is the minimum required in order to achieve the purpose for all applications. This guidance includes the necessary steps to provide evidence that certain factors have been considered within the application or annual review.

The guidance tool is currently published for consultation in use and the HRA is welcoming feedback through the survey link within the tool. If you have any queries about the CAG application process please contact the Confidentiality Advice Team.

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Research Summaries

The HRA has migrated the Research Summaries section of the NRES website to the HRA site. If you are a sponsor or researcher linked to a study and you would like the study information updated please contact the REC Manager who managed your application.

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Social Care Research Ethics Committee

The Social Care REC has been hosted by the Social Care Institute for Excellence (SCIE) for the past six years. When the HRA became a Non Departmental Public Body on 1 January 2015 we took formal responsibility for research in adult social care. The immediate impact is that we will take responsibility for the National Social Care REC but we are also looking more widely to improve the environment for research in the Social Care setting.

From 1 April 2015 the Social Care REC and its secretariat will transfer to the HRA. Research applications may be booked in the usual way through the REC Manager until this is moved to the HRA Central Booking Service in coming months.

This REC is now a firmly established feature of the social care research landscape and provides substantial support and advice to researchers in addition to its primary role of delivering research ethics opinions.

The HRA held the first of a series of listening events with the social care research community in Birmingham last month. Delegates representing social care research identified ways to take social research forward and agreed a set of priorities with the HRA.

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Presenting protocol templates

The HRA will be presenting an update on the consultation for Clinical Trial of an Investigational Medicinal Product (CTIMP) protocol guidance and template at the Institute of Clinical Research Ethics and GCP Forum on 8 April 2015.

The consultation to develop guidance and a template to assist organisations and individuals to improve the consistency and quality of their CTIMP protocols will continue until 31 May 2015. Please send any feedback to hra.protocols@nhs.net

The next phase of work is focussed on qualitative research. This protocol guidance and template will be released for comment in April 2015.

Protocol guidance and templates for other study types will be rolled out throughout 2015. If you are interested in being involved in this work please contact hra.protocols@nhs.net.

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Electronic submission in IRAS – naming of study documents

Since 19 May 2014 application forms and supporting documents for submission to NHS RECs have been submitted electronically through IRAS.

Following this successful move to electronic submissions it has become apparent that in some cases applicants are not saving the documents with an appropriate file name and are not entering a clear subtitle for the document in the IRAS checklist when uploading documents to the IRAS checklist.

This makes it difficult for REC staff and members to identify what each document is when there are several documents of the same type (e.g. multiple consent forms and information sheets for different participant groups).

Applicants and sponsors are asked to enter a clear sub-title and save supporting documents with an appropriate file name when uploading documents to the IRAS checklist. The REC Manager may contact applicants to request that documents are re-submitted with an appropriate file name before confirming that the application is valid.

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News from the National Institute for Health Research's Clinical Research Network: Ground-breaking new national service empowers public to take part in vital dementia research

A new nationwide online and telephone service that helps people to take part in dementia research studies promises to accelerate the pace of dementia research by allowing people with and without dementia to register their interest in studies, helping researchers find the right participants at the right time.

Join Dementia Research is a collaboration between the National Institute for Health Research (NIHR), Alzheimer's Research UK, Alzheimer's Society and Alzheimer Scotland and has been funded by the Department of Health.

Find out more here.

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