RESEARCHERS ENCOURAGED TO 'THINK ETHICS' FROM THE BEGINNING OF THEIR RESEARCH

Health and social care researchers often view ethics review as a hurdle to get over so they can start their research. The Health Research Authority (HRA) wants them instead to 'think ethics' from the beginning.

The HRA's new Think Ethics campaign is putting people who participate in research at the heart of ethics review by encouraging researchers and the committees that review research to focus on what really matters to those who take part in studies. It aims to make ethics review more innovative, efficient and trusted – building on many of the changes made to respond to the COVID-19 pandemic and lessons from running Research Ethics Committees with fellow regulators in Scotland, Wales and Northern Ireland.

Juliet Tizzard, Director of Policy and Partnerships at the HRA, said the work aims to make changes in a range of areas, to put people who participate in research at the heart of ethics review. It will focus on:

- clear and concise study information designed with and for participants
- fast, proportionate review focused on key ethical issues in a consistent way
- a rewarding experience for diverse, skilled and committed members
- a streamlined and user-friendly service, attracting world-leading health research in the UK

Some innovations used during the pandemic have already been introduced into the ethics review service: fast-track ethics review option for some clinical trials and virtual committee meetings. Further improvements are still to be shaped by participants, researchers, committee members and others. Once introduced, these changes will help to make the UK more attractive to researchers, increase participation in research and help attract a wider range of people to be on a Research Ethics Committee.

The Health Research Authority, along with its equivalents in the devolved administrations, oversees 84 Research Ethics Committees (REC) across the UK which provide an independent review of health and social care research studies involving people, their tissue and their data. RECs, which are made up of a mixture of expert members and lay members, provide a vital but often unseen service to health and social care research.

Ms Tizzard said: 'Researchers often describe going through research ethics review as 'getting ethics'. That's understandable, especially for studies where lots of steps are needed to set up a new research study. However, we want researchers to think of ethics as central to well-designed research with valuable outcomes. To get there, we need to change what we do. We need to be clearer about what is expected of them and what the ethics committee is looking for. And we need to make sure that committees have the same approach to decision-making, even though they might make different decisions. Think Ethics is about really making sure that ethics review is working well for researchers, patients, research participants and ultimately society.'

Read more about Think Ethics on our website.

Professor Andrew George, HRA Non-Executive Director, researcher, a former Research Ethics Committee member and himself a participant in clinical studies, chairs a special advisory group made up of academics, industry, patient and public contributors and ethics committee members which will help steer the improvements.

Professor George said:

'I have been a researcher, a member of a REC and a participant in research. I know that good ethics review is vital to ensure that research is done well and makes a difference. We need to help RECs concentrate on the key ethical issues, by giving them focused information that they need. Patients similarly need to have information that is concise and helps them make an informed decision about taking part in research. We need to get this right so that we can enable everyone; researcher, participant and REC member to work together to make it easy to do good research that improves patient outcomes.'

A string of experts will work with the HRA on Think Ethics.

Lynn Laidlaw, public contributor, said: 'As someone who lives with multiple conditions, participates in research and works with research teams as a public contributor, I welcomed the opportunity to be meaningfully involved in the Think Ethics review. People who participate in research deserve high quality, appropriate, information that details what they want to know, as well as what research teams are required to tell them. The HRA is committed to promoting patient and public involvement in research, ensuring that it meets the needs of all, broadening the concept of research ethics which traditionally focussed on protecting participants. I am excited to see what we can achieve by working together, in this ethics review.'

Dr Nicola Williams, Director of Support and Delivery at Health and Care Research Wales, said: 'We believe the ambitions of the Think Ethics programme will have a positive impact on the development and delivery of research here in Wales and across the UK and we are delighted to be a part of the initiative.'

Dr Susan Kohlhaas, Director of Research, Alzheimer's Research UK and a member of the advisory group, said: 'It's great to be part of this group that aims to streamline processes and support more research that can ultimately benefit patients and research participants.'

Professor Mary Dixon-Woods, Director of Research at THIS Institute, University of Cambridge, said: 'This initiative to align systems, processes and values relating to research ethics with what the system is seeking to achieve will be hugely valuable. I am particularly impressed with the emphasis on respect for participants is the guiding principle and with the drive for clarity, consistency and smooth processes.'

Joanne Doleman, Senior Research Governance Manager at the Wellcome Sanger Institute and Research Ethics Committee member, said: 'It's wonderful to be working with the HRA on Think Ethics. I am lucky to be in the position of being a REC member but also a researcher with significant experience of submitting research through ethics committees for review. I am excited to be involved in reviewing and improving current practices, making sure the information for participants meets all requirements, whilst also ensuring researchers receive a streamlined, efficient consistent review. This is a beneficial opportunity for everyone.'

REC chair and member of the advisory group, Sue Harrison said: 'I have been a lay REC member since 2011 and now chair my REC. Volunteering for a REC is not for the fainthearted but hugely rewarding, never more so than in the COVID 19 pandemic when we have pulled out all the stops to turn around reviews of some major strategic clinical trials, sometimes within the day. It has been fascinating to see almost instant results of our input. This, together with us leaving the EU, has highlighted for me the value of life sciences to the UK and of attracting first class research. I got involved in Think Ethics as I welcomed the opportunity to help focus on the efficacy and efficiency of the way research ethics works, for everyone's sakeparticipants, researchers, HRA approvals staff and the volunteer expert and lay members - to ensure a rewarding experience all round.'

Rasha Al-Lamee, Clinical Senior Lecturer and Consultant Cardiologist, Imperial College London and Imperial College Healthcare NHS Trust, said: 'Research is a crucial part of my work in the NHS. I see clinical research as being critically important to improving the care of my patients. In order to be able to deliver new and innovative clinical trials, I want to see the approval process streamlined so that unnecessary barriers are removed. Think Ethics provides a unique opportunity to reshape the ethics application and review process so that good research can be encouraged and facilitated.'

Researchers can expect to hear more about Think Ethics over the next few months including opportunities to feed into the work. To find out more, please email engagement.team@hra.nhs.uk.

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For further information, please contact Alison Barbuti, HRA Communications Manager, alison.barbuti@hra.nhs.uk

About the HRA

The HRA is one of a number of bodies responsible for the regulation and governance of health and social care research in the UK.

Our vision is for high-quality health and social care research that improves people's health and wellbeing, and our core purpose is to protect and promote the interests of patients and the public in health and social care research.

To achieve this, we:

- make sure that research is ethically reviewed and approved
- promote transparency in research
- oversee a range of committees and services and

• provide <u>independent recommendations</u> on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects. More information can be found at <u>hra.nhs.uk</u>.