

We make it easy to do research that people can trust

Strategy 2022-25



Foreword

Matt Westmore, Chief Executive



Picture...

...a **diabetes patient** who juggles a job and caring responsibilities. They've got limited time and energy to engage with their treatment, let alone research.

...an **older person** with several health conditions, being well cared for but in a fragmented and hard pushed care setting – with multiple providers.



...someone from a **community** whose needs are often underrepresented and underserved by health or social care research and services.



Can research better meet their needs?

The HRA was established ten years ago to transform UK research regulation and governance and we have done that. We have better supported the research community, while putting people first.

During the pandemic, we were able to respond quickly, without lowering our high standards, approving studies in hours that would normally take weeks. That enabled UK researchers to make the single biggest contribution to the global fight against COVID-19.

The UK is amongst the best places to do research in the world, with outstanding science, globally successful companies, our national health and social services and strong public support. Fundamental to our success is trust, meaning that people want to get involved in research and use its findings. Cementing our status as a destination to do world-leading research with public confidence will attract investment, creating more research opportunities for patients and the public and helping us to better meet their needs.

This strategy is focussed on earning and maintaining people's trust in research. By working in a balanced and proportionate way we will make it simple and fast to deliver research that people can trust. It sets out two principles that guide our work – include and accelerate – and how we will make these happen – using digital technology well and always looking for ways to do things better.

We cannot deliver this on our own. The HRA is a community, and we work in partnership across the UK, between regulators, other agencies, the research community, and above all with people.

Our community includes employed staff and many people who give their time generously, and in many cases freely, to sit on committees, advise and get involved to make a difference to research in the UK and peoples' lives.

Through this strategy, together, in partnership, as a community, we will make it easy to do research people can trust.

Our vision is for high quality health and social care research today, which improves everyone's health and wellbeing tomorrow.

We help realise this by making it easy to do research that people can trust.

Over the next three years, we will be guided by two principles. To include, so that health and social care research is done with and for everyone, and to accelerate, so that research findings improve care faster because the UK is the easiest place in the world to do research that people can trust.





Include

**Health and social care research
is done with and for everyone.**



Include everyone in research

Meaningfully involving people in all stages of research and sharing its findings is crucial to earn people's trust. It helps us do better research that can improve care.

We will:

- Push for change to increase diversity and inclusion in research
- Increase public involvement in research
- Make transparency the norm for research

Ask you what you want research to look like and act on this

Research must address the issues that matter to you to earn your trust.

We will:

- Champion issues that are important to people in research
- Create public conversations about research issues that matter to people
- Encourage researchers to do a better job of putting people first

Involve you in the HRA

We can make better decisions by working with a diverse group of people with lived experience and making sure that anyone who wants to can get involved.

We will:

- Increase public involvement in how we make decisions
- Listen to and involve a diverse group of people in our work
- Talk in a way that everyone can access and understand



Accelerate

Research findings improve care faster because the UK is the easiest place in the world to do research that people can trust.



Save money and time so that you can focus on doing good research

To earn people's trust, research projects involving people, their tissue or their data need a number of approvals before they can go ahead. We will make it easier for researchers to find out what they need to do and earn these approvals.

We will:

- Join up research approvals across the UK
- Make it easier to put people first in research
- Support action to ensure that precious NHS resources are focussed on research that will help improve care



Create a new online system to help you make research happen

The approvals that each research project needs come from different organisations depending on what it is trying to do.

We will:

- Connect the steps that are part of doing research and make them easy to follow.
- Work with others so that each step you take informs the next



Support new ways to do research

We will make it possible to do new types of research here in the UK so that we can get better, quicker answers and put people first.

We will:

- Work with research teams to explore new ways to do research and make these happen
- Learn together to make sure that regulation keeps up with research so you can trust our decisions



Lord Kamall,
Parliamentary Under
Secretary of State
(Minister for Technology,
Innovation and Life Sciences)

“ Making it easier to conduct high quality research that people can trust, by partnering with patients and the wider public, will make the UK a hub to deliver more world-leading, life-changing breakthroughs in science which will also improve the health of our nation.

Through this strategy, the HRA will help deliver our vision for the UK to be the best place in Europe to invest in a life-science business, bolstering our economy and status as a science superpower and improving patient care. ”





Include:

Health and social care research is done with and for everyone.

Include everyone in research

Meaningfully involving people in all stages of research and sharing its findings is crucial to earn people's trust. It helps us do better research that can improve care.

We will:

- Push for change to increase diversity and inclusion in research
- Increase public involvement in research
- Make transparency the norm for research



Health and social care research conducted with and for everybody can help us address health inequalities.

“ Reducing health inequalities and keeping people in better health for longer is in everyone's interest – it is good for the individual, families, society, the economy and NHS. ”

**Professor Sir Chris Whitty,
Chief Medical Officer**

[DHSC press release \(2021\) New era of public health to tackle inequalities and level up the UK](#)





We want to help more researchers to involve the public in a meaningful way in their research from design through to dissemination of the results.

A quarter of researchers applying to the HRA still say that they have not involved the public in the design of their research, despite this being an expectation set by Research Ethics Committees.

(Based on an analysis of all applications to UK Research Ethics Committees to conduct research excluding tissue banks and databases stating that they have not involved the public in their IRAS form over a six-month period from September 2021 to February 2022.)



“ It is reassuring to know that the Health Research Authority is working to make sure that all trials are registered so that I can find out about opportunities to be involved in research that I can trust, which is not only helpful to me, but lots of other people too. ”

Mark Holden,
Public contributor

12% of clinical trials are not registered and 25% of clinical trials of medicines are not reported. We are changing that.

(Reference: HRA (2021) Research Transparency Annual Report 2021)





Ask you what you want research to look like and act on this

Research must address the issues that matter to you to earn your trust.

We will:

- Champion issues that are important to people in research
- Create public conversations about research issues that matter to people
- Encourage researchers to do a better job of putting people first



“ Patients and participants are the foundation of clinical research. Without them research can't happen and healthcare can't improve.

'...Our vision is to make research open to everyone and to make participation in research as easy as possible. ”

Department of Health and Social Care, The Executive Office (Northern Ireland), Scottish Government, Welsh Government, (2021)

Saving and Improving Lives: The future of UK Clinical Research Delivery



“ I've often been faced with ethical issues in research and think public involvement has an important role in this area. Members of the public bring their humanity to the discussion, particularly their empathy and emotional intelligence. ”

Louise Vale, public contributor involved in patient research for over 10 years



Involve you in the HRA

We can make better decisions by working with a diverse group of people with lived experience and making sure that anyone who wants to can get involved.

We will:

- Increase public involvement in how we make decisions
- Listen to and involve a diverse group of people in our work
- Talk in a way that everyone can access and understand



“ If I wasn’t here, you wouldn’t know my story. I don’t want to be the only black person in the room this time next year. ”

Dolapo Della Ogunleye,
Public contributor and cancer patient

“ Community engagement is very important, particularly for those for whom English is a second language, many of whom may currently be underserved by health and social care. People trust their community. Researchers, organisations like the Health Research Authority and community members can develop new ways of working together that work for them, opening up opportunities for people to be involved in research that they can trust. ”

Circle Steele,
Chief Executive Officer at the Wai Yin Society





Accelerate:

Research findings improve care faster because the UK is the easiest place in the world to do research that people can trust.



Save money and time so that you can focus on doing good research

To earn people's trust, research projects involving people, their tissue or their data need a number of approvals before they can go ahead. We will make it easier for researchers to find out what they need to do and earn these approvals.

We will:

- Join up research approvals across the UK
- Make it easier to put people first in research
- Support action to ensure that precious NHS resources are focussed on research that will help improve care



Combined review with the MHRA, the new way that all trials of medicines are approved, is on average **twice as quick as two separate systems were.**

Reference: This performance data is taken from timelines for CTIMPs going through separate and combined review from 2018 to present (to February 2022). Combined review halves the time it takes for studies to get approval and cuts the time from application to recruiting a first patient by 40 days



“ The efforts put in by the HRA and MHRA to streamline clinical research in the UK have resulted in an improved environment for setting up clinical trials in the UK and an efficient combined regulatory review of studies, shortening national approval times. Further work is now needed so that these efficiencies are realised at a local level through consistent and efficient site set up.

The creation of the national costings framework ensures that all hospital trusts, health board and GPs are working with the same structure and the future roll out of the national costings review should enhance this further once fully embedded into national process, saving time and resources for both the sponsor and NHS. ”

Sophie Gillmore,
Director, Site Management & Monitoring - Clinical Operations, AstraZeneca

“ Any of us who have been ill or had family members needing clinical care know that it’s a time of anxiety and uncertainty – the opportunity to be part of research should help to alleviate some of the stress rather than add to it. That means we should make it easy for people to participate by understanding what matters to them, and what practical and clinical arrangements would make it easier for people to take part. For researchers, that is going to mean a fairly radical change in practice – but surely the result will be more representative research and considerably better care. ”

Dr Sarah Williams,
Associate Director of Research & Improvement, Solent NHS Trust



HRA Approval brings together research ethics review and governance and legal review, meaning that researchers wanting to do research in England and Wales can submit one application for both. Before this, local governance and legal checks were repeated at each place where research was going to take place.

Model agreements: We've created template agreements that save time setting up research studies and that make sure that the interests of people taking part are protected and promoted. This increases the speed and efficiency of study set-up while protecting everyone's interests.



“ There are a lot of moving parts to get research off the ground, with multiple organisations requiring detailed information before they can approve the research to go ahead. Action to streamline the process based on individual trial risk will help us focus on what really matters, making it easier to navigate without impacting trial conduct safety. The aim is to get the research underway so that we can better understand disease and improve health care. ”

**Professor Saul Faust, FRCPCH, PhD,
Director, Southampton NIHR Clinical
Research Facility and Clinical Director, NIHR
Wessex Local Clinical Research Network.**

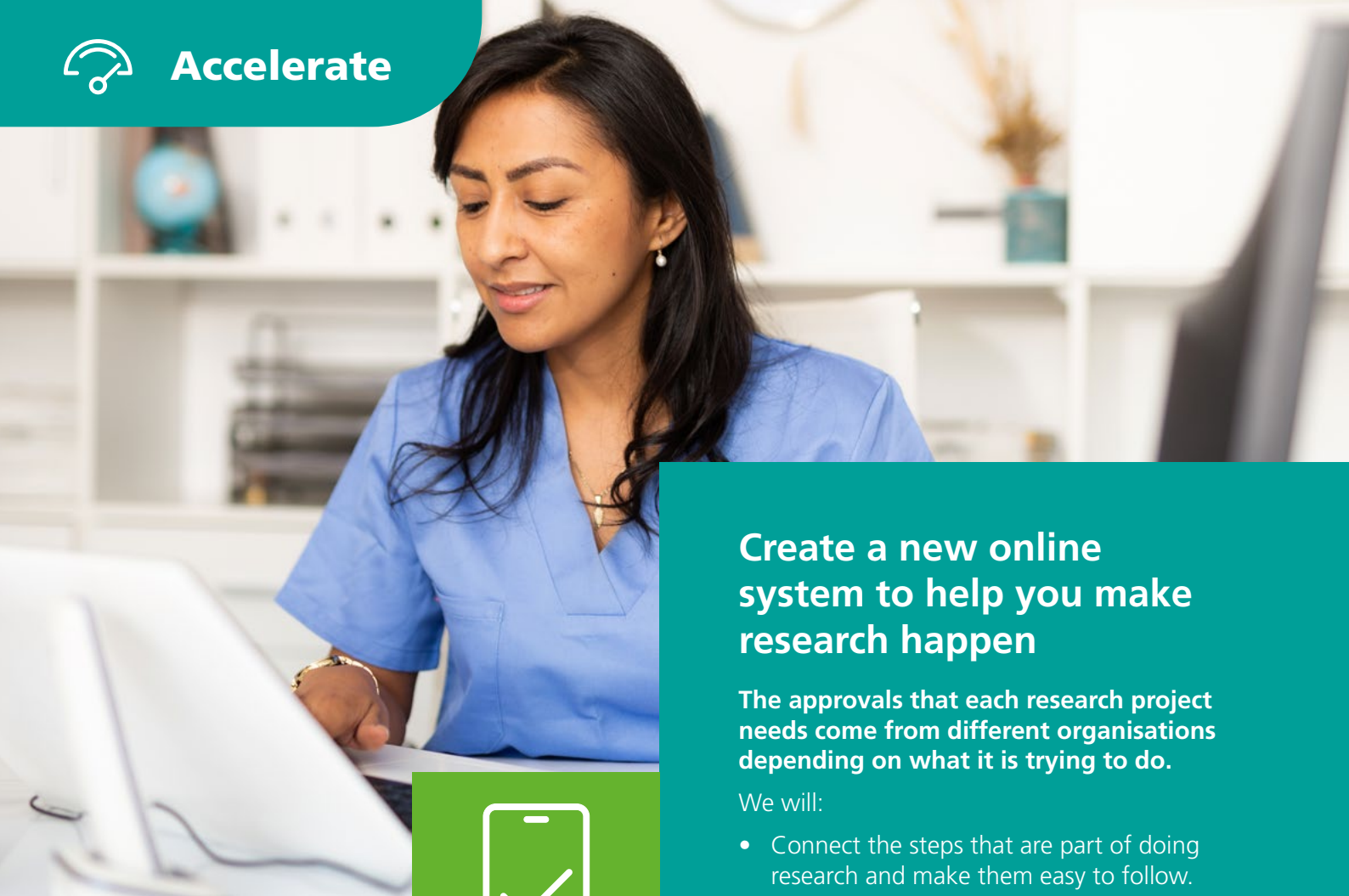
“ The strategy's focus on joining up research approvals across the UK will help reduce research bureaucracy and waste, speeding up the time it takes for scientists to get research studies up and running.

“This will allow more time, funding and resources to be directed towards the research itself, where it will make the most difference to patients. This will, in turn, reassure charities' donors that their money is being used wisely and in a cost effective way.

“The new process benefits everyone by reducing duplication and maintaining a robust system. Researchers can invest more of their time developing life-changing treatments and innovations. These will reach patient communities faster and, ultimately, save and improve more lives. ”

**Nicola Perrin MBE,
Chief Executive of the Association of Medical
Research Charities**





Create a new online system to help you make research happen

The approvals that each research project needs come from different organisations depending on what it is trying to do.

We will:

- Connect the steps that are part of doing research and make them easy to follow.
- Work with others so that each step you take informs the next



“ We are excited to continue work with the HRA on developing a research environment that puts users at its heart. From the setting up of research projects to the sharing of findings – we want to make it easier for important research to be conducted in the UK that people trust. Through our partnerships, we can create a world- leading research system that works for everyone. ”

Dr Martin O’Kane,
Deputy Director, Clinical Investigations and Trials, Medicines and Healthcare products Regulatory Agency

“ A world-class regulatory system for all health and social care research is key to making the UK the easiest place in the world to do research that people can trust. I look forward to continuing to work closely with the HRA and colleagues in Scotland and Northern Ireland as we develop future IRAS together. ”

Dr Nicola Williams,
Director of Support & Delivery, Health and Care Research Wales





“ The research community in Scotland is committed to working together with its partners across the UK to create a world-class environment for health and social care research. It is vital we work together to support researchers throughout the lifecycle of a project, from planning and placement through to set-up and delivery, and the new strategy from Health Research Authority will underpin this important work. ”

Dr Charles Weller,
General Manager, NHS Research Scotland (NRS)



“ The partnership between NIHR and HRA is a fundamental building block to successfully delivering the end-to-end research pathway. The opportunity to create more automated interoperability between the core systems of the NIHR and HRA underlying this pathway is of critical importance. It creates an opportunity to further accelerate the delivery of key research which could lead to making a difference in more people’s lives sooner. ”

John Nother,
Chief Digital Officer, National Institute for Health Research

Experiences of the first new services to be rolled out demonstrate the potential of a new online system

“ I have never used the IRAS form, however I was quickly able to identify the tools which clearly highlighted how each question should be answered. It prompts you to consider details you might not yet have thought about. ”

“ I love the e-booking system. I had trouble accessing the phone line booking in the past, this is just so much easier! ”

Research applicant 2022





Support new ways to do research

We will make it possible to do new types of research here in the UK so that we can get better, quicker answers and put people first.

We will:

- Work with research teams to explore new ways to do research and make these happen.
- Learn together to make sure that regulation keeps up with research so you can trust our decisions.



“ Research is fundamental to the transformation of the NHS and improving patient care. In addition facilitating research to happen quickly and predictably will bolster our economy and status as a science superpower, and also drive innovation. ”

Dr Timothy Ferris,
National Director of Transformation,
NHS England



Approving a world-first

In February 2021, we approved the world’s first COVID-19 human infection challenge study to take place here in the UK.

We assembled a specialist Research Ethics Committee to review the research proposal to ensure that the interests of the people taking part were considered throughout. Their review helped improve the research and meant that those taking part could be confident that they will be well informed and looked after.



“ Recent innovations in trial design, including the ability to do adaptive trials and modular trials for great flexibility and being able to decentralise trials to reduce or eliminate the need for patients to travel to specific sites to take part, can make better use of resources such as time and money and open up opportunities to be involved in research to more patients. But we can only realise the potential of these new approaches if the public has the confidence that they can trust this research. ”

Professor Ruth Plummer,
Clinical Professor of Experimental Cancer
Medicine, Newcastle University

The change that you will see

By 2025, we will make it easier to do research that people can trust:

These are high-level milestones that we plan to deliver. We will provide further detail, including how we will measure our success, in our annual business plans.



Include: Health and social care research is done with and for everyone.

Include everyone in research

More diverse groups of people with relevant lived experience are involved in all stages of research and are able to take part, with the findings shared publicly so that they can be used to improve care.



2022-23

- Deliver 'Make it Public' conference and report to share best practice and maintain momentum to make transparency about research the norm. (To be delivered annually)
- Coordinate action by the health and social care research sector to deliver our shared commitment to embed public involvement.

2023-24

- Implement new requirements for clinical trials.
- Develop ways to assess researcher's performance on transparency about research and policy on applying sanctions
- Make it easier for Research Ethics Committees to share insights from good public involvement in the research they review, and to challenge poor involvement.

2024-25

- Improve the diversity and inclusion of people taking part in research.
- Deliver 'Make it Public' ambitions on registration so that information about clinical trials is made public before the research begins.
- Make sure that all research teams feed back to participants so that people taking part in research are given information about its findings.



Ask you what you want research to look like and act on this

It is easier to put people first in research.

2022-23

- Better support members of the public who have questions and concerns about health and social care research.

2023-24

- Make changes to the standards that we expect the information given to people taking part in research to meet, and how we assess this. This will improve informed consent and make it easier for researchers to develop this information and ethics review committees to review it.
- Deliver a programme of public facing activities so you can tell us what matters to you about research and we can act on this.
- Establish mechanisms to reach diverse groups of people including those that are currently under-served by research to hear what they want research to look like and act on this.

2024-25

- Push for changes that make it easier to put people first in research.



Involve you in the HRA

We make better decisions, informed by a diverse group of people with lived experience.

2022-23

- Create more opportunities for people with lived experiences to be involved in our internal decision making.

2023-24

- Include a more diverse group of people in our regulatory decision-making committees
- HRA communications and engagement help people find out what the HRA is doing and why it matters.





Accelerate: Research findings improve care faster because the UK is the easiest place in the world to do research that people can trust.

Save money and time so that you can focus on doing good research

It is easier for researchers to find out what they need to do and earn the approvals for their research to go ahead.



2022-23

- Support action to ensure that precious NHS resources are focussed on research that will help improve care

2023-24

- Make changes to how we regulate and review research so that it is more proportionate and focuses on the issues that matter most to people.





Create a new online system to help you make research happen

A new online system is helping researchers take the steps needed to make their research happen.

2022-23

- Put human-centred design at the heart of the new Integrated Research Application System (IRAS) – an online system which allows researchers to make one application for research anywhere in the UK.

2023-24

- Regularly update the new system to keep improving it.
- Automatically share data with other organisations involved in approving and delivering research so that researchers do not have to submit the same information multiple times.

2024-25

- Continue improving our services to help make research happen.



Support new ways to do research

The UK is a destination to do new types of research that people can trust.

2022-23

- Offer a tailored service for researchers to explore new ways to do their research and help them navigate the system to do this
- Create an HRA change and innovation function so we always keep pace with changes in research.

2023-24

- Support new types of digitally-enabled and decentralised research, making sure that regulation keeps up so it is clear what researchers need to do to earn public trust and make the research happen.
- Support research at every stage of a patient journey through the new Integrated Care Systems.

How we will do this

We will:

- Use digital technology well to do our work
- Always look for ways to do things better

The way that we work



Joining up and connecting across the system and the UK



Being clear what good looks like and setting the standard



Making sure that research meets these standards



Working in partnership with people and communities with lived experience



Working in partnership with the research community



Driven by equity, inclusion, integrity and transparency to get the best value from every penny spent on research



Use digital technology well to do our work

We will design, create and support simple to use, accessible systems that make it easier for researchers to do trusted research and for patients and the public to find out about that research. We will:

Design our digital systems in a human-centred way

- work with our users to create technology that is easy for them to use and helps them do research that people can trust
- create diverse teams that care about making better our users' entire experience of working with us
- use digital systems and data to help us learn and improve what we do

Automate and join-up processes where this will improve our work

- automate processes where this will improve the experience for our users
- save money and improve consistency by automating repetitive, administrative tasks
- increase compliance and cyber security



Always look for ways to do things better

Our people deliver our strategy. We will enable a diverse and inclusive organisation giving our people the tools and support that they need to do so, we will:

Always learn, improve and innovate

- embed a learning culture where learning opportunities are meaningful and help us deliver our mission
- encourage and support people to develop new ideas improving how we work and get things done
- use a variety of techniques to create, test and put in place improvements

Be a great place to work

- deliver our people strategy where everyone is supported to be their best, is valued, and is proud to be part of the team
- involve our staff in the HRA and take action to support their well-being
- be empowered by a deep understanding of our social mission; to make it easier to do research that people can trust

Commit to environmental sustainability and achieving net zero

- reduce our carbon usage and waste.
- support our people to make changes that reduce their carbon usage and waste.
- re-use and repair where possible to support a circular economy



About us

The Health Research Authority is an independent arm's length body of the Department of Health and Social Care. We were set up in 2011 with a mission to protect NHS patients, your tissue and your data when you are involved in research.

We have more than 250 staff in England including offices in London, Bristol, Newcastle, Manchester and Nottingham. They're supported by our community of around 850 people who volunteer their time generously to help us to deliver our services, and members of the public who advise us on our work. The HRA's Board leads the organisation and makes decisions that affect our work. The Board approved this strategy.

To make it easy to do research that people can trust, the HRA:

- works with people to understand what you want research to look like and acts on this so that you can trust research
- makes sure that people taking part in research are treated ethically and fairly, by reviewing and approving health and social care research studies that involve people, their tissue or their data before they can start
- champions research transparency, so that you can always see when research is taking place, or the results of that research if it has finished
- works with other organisations across the UK to make sure that, wherever you are, research studies can be set up smoothly and are always subject to the same scrutiny before they start
- is one of the gatekeepers of patient data, making sure that your information is protected if it's used for research





Health Research
Authority

