

Making research everybody's business: a position statement of the Royal College of Physicians and the National Institute of Health and Care Research

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Introduction

The COVID-19 pandemic has starkly illustrated the importance of clinical research. The development of effective vaccines and discovery of treatments such as dexamethasone have saved millions of lives globally and will be fundamental to our ability to live alongside the SARS-CoV-2 virus in the years ahead.

Research into other conditions has been severely impacted. During the first wave of the pandemic, over 40% of NHS trusts had non-COVID-19 research studies paused. As waiting times for diagnosis and treatment have reached record levels, the intense pressure on the NHS continues to impact on our capacity to undertake research: it has been necessary to redeploy many research staff and clinical academics to provide direct patient care during the crisis.

Clinical research is essential to improving care and outcomes for patients. This is recognised in the NHS Long Term Plan³ and the government's *Saving and improving lives: the future of UK clinical research delivery* vision document.⁴ It describes research as 'the single most important way in which we improve our healthcare – by identifying the best means to prevent, diagnose and treat conditions'. Evidence also indicates that patients have better outcomes in research-active hospitals, even if they are not involved in trials themselves.⁵ By improving the efficiency and efficacy of care, clinical research can be a vital tool in tackling waiting list backlogs and reducing the pressure on the NHS.

All healthcare professionals can play a role in supporting research, and they value the opportunity to do so. A member survey conducted by the Royal College of Physicians (RCP) in 2020 found that the majority of physicians (57%) wanted to be more involved in research.⁶ The General Medical Council (GMC) has highlighted that

there are a variety of ways in which doctors and other healthcare professionals can engage with research,² including by:

- > helping patients to understand relevant research or access clinical trials
- > working with research teams to recruit patients into important research studies
- > consenting patients for research
- > working on local clinical research initiatives
- > initiating and developing new research ideas based upon their clinical insights
- > pursuing medical academic careers
- > providing leadership
- > disseminating research findings, explaining them to patients and incorporating research evidence into practice.

Recovering clinical research activity following the disruption caused by the pandemic is a challenge that requires a collective response across the health and care system, at both national and local levels, and across primary, secondary and community care. Together we need to develop a strategic, integrated approach that serves local, regional and national populations. It must spread the benefits of research equally across the UK, improving access and outcomes for underserved communities and helping to reduce health inequalities. It is also important to recognise the central role that clinical research plays in a wider research ecosystem, which begins with discovery science and ultimately leads to the adoption of new techniques and treatments – the recovery of research activity is crucial to maximising the benefits that this process delivers for patients.

This position statement makes recommendations for a range of stakeholders (summarised in Table 1) – including trusts and integrated care systems (ICs), NHS England (NHSE) and Health Education England (HEE), regulators and funding bodies, as well as equivalent authorities in the other UK nations – with a view to making research part of everyday practice for all clinicians. Ultimately, the events of recent years have shown clearly that **research needs to be normalised as core business in the NHS, especially in the most difficult of times, as research for all.**

Health and Care Act 2022

In England, the Health and Care Act 2022 has enhanced the health service's responsibilities with respect to clinical research in several important ways. The legislation achieves this by:

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Table 1. Summary of recommendations

For trusts, health boards and integrated care systems (ICSs)	<ul style="list-style-type: none"> > Develop strong links between medical directors, R&D directors and chief executives > Encourage support for research to be recognised as part of direct clinical activity and reward involvement of such through local and national awards > Ring-fence time for research in job plans of those who want to have a substantive research leadership role > Ensure that multidisciplinary workforce planning encompasses those who support research > Take opportunities to implement proportionate training requirements for those involved in research (including taking account of MHRA and HRA's joint statement on the application of Good Clinical Practice)¹
For HEE, NHSE and equivalent bodies in the other UK nations	<ul style="list-style-type: none"> > Work with stakeholders to promote opportunities for postgraduate doctors, medical students and other health professionals to engage with research > Recognise and reward trusts that engage with research and industry to improve patient care
For regulators	<ul style="list-style-type: none"> > For the CQC: strengthen assessment of clinical research activity as a marker of care within assessment processes for trusts and ICSs > For the GMC: build on the publication of its key principles² – which set out system changes needed to encourage engagement with research – by continuing to work with partners to encourage greater participation
For funders	<ul style="list-style-type: none"> > For the NIHR: continue to build capacity and capability for research across the whole of the NHS and care, working closely with other funders, academies and cross-funder initiatives > Ensure that grant awards and research processes recognise and support research that addresses health inequalities and other NHS priority areas > Ensure that research projects that are funded are accessible and inclusive > Provide support to grant-holders to reduce the environmental impact of clinical research activity

- > strengthening NHSE's duty to 'facilitate or otherwise promote' research and use of evidence obtained from research, as laid out in the Health and Care Act 2022
- > requiring NHSE to explain, in its business plans and annual reports, how it proposes to meet this duty
- > putting integrated care boards (ICBs) – which will play a key role in the operational delivery of these new responsibilities – on

a statutory footing and placing the above duties on them too as detailed in the statutory guidance on the preparation of integrated care strategies⁷

- > requiring NHSE to review how ICSs deliver their duties on an annual basis

The provisions in the Act create new opportunities to embed research in clinical practice, and underscore the need for this to be a significant area of focus across the NHS as the transition to ICSs takes place. This statement includes a number of recommendations applicable to ICSs that would help to maximise the impact of the new research mandate and ensure that it is implemented effectively.

While the scope of the Act specifically covers England, many of the recommendations made in this statement are also relevant to the other UK nations and should be considered by equivalent authorities in Scotland, Wales and Northern Ireland.

Recommendations

In order to improve engagement with research and make this part of everyday practice for all clinicians, we make the following recommendations for stakeholders across the health and care system.

For trusts, health boards and ICSs:

- > **Develop strong links between medical directors, R&D (research and development) directors and chief executives:** Securing buy-in for clinical research at senior level is essential to creating a positive research environment and realising the benefits of research for patients and staff. Building relationships between medical directors, R&D directors and chief executives – within organisations and across systems – is a fundamental part of this, providing a platform to embed research in practice more widely. This is also vital for developing effective external partnerships with universities – something the Academy of Medical Sciences has identified as crucial to accelerating the translation of research into patient benefit⁸ – as well industry and other national and international partners.
- > **Encourage support for research to be recognised as part of direct clinical activity and reward involvement of such through local and national awards:** All clinicians can play a role in supporting the delivery of clinical research as part of their everyday practice, for example as a principal investigator in a study. One opportunity to promote this is by recognising support for research as part of direct clinical activity – given the substantial benefit that research can have for patient care and outcomes. This is something that individual trusts should consider encouraging. The contribution of clinicians who have been involved in impactful research should also be acknowledged and rewarded through local and national awards.
- > **Ring-fence time for research in job plans of those who want to have a substantive research leadership role:** For clinicians who wish to build a career in research and take on a substantive leadership role – such as a chief investigator – ring-fencing protected time in their job plan should be considered to support their development. This will ultimately be a matter for local negotiations around job planning or with funders. A letter sent from health leaders to NHS chief executives in England in May 2022 on the release of medical colleagues for the purposes of carrying out work for the wider health system highlighted the

value that time allocated in job plans to causes such as research has delivered during the pandemic.⁹ It is vital to ensure that clinical research is inclusive and that opportunities to pursue a research career are accessible for everyone, regardless of their background.

- **Ensure that multidisciplinary workforce planning encompasses those who support clinical research:** There have been significant pressures on the workforce that supports the delivery of clinical research for some time, as a result of the pandemic and the need to reduce waiting lists. Action is needed to increase capacity, to enable research support staff to develop new skills in areas such as digitalisation and data science that are necessary to take advantage of innovation opportunities, and to maximise the contribution that members of the wider health workforce – such as physician associates, radiology, pharmacy and laboratory staff – can play in clinical research and supporting interventional medicinal clinical trials. As a first step, trusts, health boards and ICSs should ensure that their workforce planning includes those who support the delivery of clinical research.
- **Take opportunities to implement proportionate training requirements for those involved in research:** It is essential that everyone who is involved in clinical research is appropriately trained to undertake the tasks required of them. Equally, training requirements must be proportionate – trusts, health boards and ICSs should take all opportunities to ensure this is the case, so that training requirements do not inadvertently become a barrier to research. As part of this, they should take account of the joint statement by the Medicines and Healthcare products Regulatory Agency (MHRA), Health Research Authority (HRA) and administrations in the other UK nations which specifies that training in Good Clinical Practice is not required unless researchers are involved in clinical trials of investigational medicinal products (and can be proportionate even in that instance).¹

For HEE and NHSE, as well as statutory education bodies and the departments of health in the other UK nations:

- **Work with stakeholders to promote opportunities for postgraduate doctors, medical students and other health professionals to engage with research:** Engaging medical students, postgraduate doctors and other health professionals in clinical research at an early stage enables them to build experience that they can draw on throughout their career. HEE and other statutory education bodies should work with stakeholders at all levels – such as deaneries locally and royal colleges nationally – to ensure that these groups can access opportunities to participate in research. Initiatives such as trainee research collaboratives, flexible portfolio training and NIHR's associate principal investigator scheme support the development of the skills and experience needed to undertake research.
- **Recognise and reward trusts that engage with research and industry to improve patient care:** In 2019, the NHS Long Term Plan indicated that performance on adopting proven innovations and on research would become part of core NHS performance metrics, assessment systems and benchmarking data.³ This provides an important mechanism for recognising research-active trusts. NHSE should explore what opportunities are available to reward trusts that perform highly on these metrics, to further incentivise engagement with research. The departments of health in the other UK nations should consider

what equivalent levers are available to recognise and reward research activity in Scotland, Wales and Northern Ireland.

For regulators:

- **For the Care Quality Commission (CQC): strengthen assessment of clinical research activity as a marker of high quality care within assessment processes of trusts and ICSs:** In 2019, the CQC began to take account of research when inspecting trusts by including questions about clinical research activity within its well-led framework.¹⁰ Recognising the positive impact that research has on patient care – and working with other stakeholders, including NHSE as it leads the development of new metrics and system oversight – the CQC should further strengthen the position of clinical research within its new regulatory model and assessment methodology to ensure that trusts and systems are encouraged to be research active.
- **For the GMC: build on the publication of its key principles by continuing to work with partners to encourage greater participation:** The GMC has published key principles describing the system changes that will help doctors and healthcare teams to engage with and support more research as part of their clinical practice.² The GMC should continue to work closely with partners in the education, health and research sectors to encourage greater participation in and a more inclusive approach to research in clinical practice.

For funders:

- **For the NIHR: continue to build capacity and capability for research across the whole of the NHS and care, working closely with other funders, academies and cross-funder initiatives:** The benefits of clinical research are not felt equally across the UK. Access to research opportunities needs to be improved for patients and clinicians in communities that have been historically underserved. NIHR has an important role to play in developing the infrastructure and capacity necessary to increase research activity in these areas and in ensuring that this encompasses all of health and social care, and should work with other funders, academies and cross-funder initiatives such as the Clinical Academic Training Forum to achieve this.
- **Ensure that grant awards and research processes recognise and support research that addresses health inequalities and other NHS priority areas:** Tackling inequalities in health outcomes represents an urgent challenge for all those working in health and care. It is crucial that clinical research plays its part in reducing health inequality, the causes of which are often complex and long term. In order to facilitate this, research funders must ensure that health inequality is a priority within grant-making, and that awards, funding and subsequent research processes all address inequalities.
- **Ensure that research projects that are funded are accessible and inclusive:** Improving equality, diversity and inclusion within clinical research and widening participation – in terms of both who conducts research trials and who takes part in them – is essential to ensuring that the benefits of research are felt by everyone. Funders should therefore ensure that the projects they support are accessible and inclusive, and provide guidance to grant-holders on how to improve inclusivity in their work, such as that available through the NIHR INCLUDE project.¹¹ Patient and public involvement in clinical research is ultimately crucial to its success and the shared commitment to

improve public involvement in research, supported by many UK funding bodies, provides an important standard in this regard.¹²

- **Provide support to grant-holders to reduce the environmental impact of clinical research activity:** As research becomes more embedded in clinical practice, it is vital that this is achieved in a way that supports the NHS's wider net zero targets. Clinical research activity can be a significant source of CO₂ emissions, with one study, based on a sample of 12 randomised controlled trials, finding that the average CO₂ emission per trial was 78.4 tonnes.¹³ Funders should provide support to their grant-holders to reduce the environmental impact of their work, such as the carbon reduction guidelines developed for researchers by NIHR.¹⁴ ■

Note

This position statement has previously been published on the RCP website.¹⁵

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