



Committee Stage Briefing – Health and Care Bill

An opportunity to embed research within the NHS

Clinical research activity in the NHS delivers clear benefits to patients, such as improved outcomes and lower mortality rates, as well as to the NHS and the broader economy.

The [Health and Care Bill](#) provides a once-in-a-decade opportunity to embed research at the heart of the NHS, by putting this ambition on a statutory footing.

However, the legislation as proposed in ‘*Clause 20, 14Z40 - Duty in respect of research*’ only includes a duty to promote research, maintaining the status quo from the 2012 Health and Social Care Act. This is a missed opportunity.

Our organisations are supportive of amendments which enhance the existing duty by:

- a) Ensuring that eligible organisations for which the Integrated Care Board is responsible conduct research.
- b) Requiring Integrated Care Boards to outline how they have, or plan to discharge such duties for research in a) their annual reports and b) joint forward plans.

A strengthened legislative mandate, which moves beyond the current *duty to promote research*, will support patients, clinicians and NHS organisations across the country having equal access to the well-documented benefits brought by research participation.

Benefits that a strengthened mandate would help to deliver include:

- Delivering improved patient outcomes and experience
- Increasing NHS staff satisfaction
- Delivering economic benefits for the NHS and the broader economy
- Supporting Levelling-up and our ability to address health inequalities
- Enhancing the UK’s status as a science superpower

[The Future of UK clinical research delivery vision](#) outlines that the **“NHS will be encouraged to put delivery of research at the heart of everything they do, making it an essential and rewarding part of effective patient care”**. Therefore, these amendments are needed to deliver on the ambition shared by the Government and the UK’s research and life sciences community for the UK to become the destination of choice for clinical research.

Amendments we support

Amendment 79 Clause 20: *Lord Sharkey, Lord Kakkar, Lord Patel, Baroness Blackwood*

This amendment requires ICSs to ensure that eligible organisations for which the Integrated Care Board is responsible conduct research and requires ICSs to outline how they have, or plan to discharge such duties for research.

Amendment 81 Clause 20: *Baroness McIntosh*

This amendment requires ICBs to outline how they have, or plan to discharge such duties for research.

Amendment 96 Clause 20: *Baroness McIntosh*

This amendment requires ICBs to conduct research by ensuring requests from organisers of authorised clinical trials are considered and patients are offered the ability to participate.

Amendment 196 After Clause 61: *Lord Sharkey, Baroness Blackwood*

This amendment requires NHS Trusts and NHS Foundation Trusts to conduct research and requires them to outline how they have, or plan to deliver research.

Why is legislation needed, and why now?

The [Health and Care Bill](#) provides a once-in-a-decade opportunity to embed research at the heart of the NHS. The last major NHS legislation was passed 9 years ago, and to set the tone for the decade ahead, it is critical that the opportunity presented by Health and Care Bill is not missed.

Alongside the legislation and forthcoming NHS reforms, the response to COVID-19 has seen more patients, NHS staff and sites engaging in research than ever before. Legislation presents a **unique opportunity to not only retain, but build upon the research-active NHS culture we have seen in response to COVID-19.**

Research in the NHS is supported by funders across the entire ecosystem for the benefit of patients. In 2020/21 around 1.4m participants took part in clinical research across England sponsored by charities, industry, academia and other public funders. This was almost double the number that took part the previous year, with increases driven by major COVID-19 research studies.

The combination of the Vision for Clinical Research, the learnings from COVID-19 and the Health and Care Bill provides us with a **time-limited opportunity to lay the foundations which will truly transform clinical research in the UK** for the benefit of patients, NHS staff, and the UK economy. These benefits are well recognised:

Patient benefits

The **benefits for patients treated in research-active NHS organisations are well documented, with [evidence](#) showing that patients treated in these settings have improved**

outcomes, [lower mortality](#) rates and [increased](#) confidence in the care being delivered, with NHS organisations seeing improved Care Quality Commission ratings.

NHS staff benefits

A strong body of evidence shows that **engaging in research [improves job satisfaction](#) amongst health workers, boosts staff morale and can [reduce burnout](#).**

57% of doctors [surveyed](#) by the Royal College of Physicians (RCP) said they would like to be more involved in research. 67% of those surveyed said having dedicated time for research would make them more likely to apply for a role. Care Quality Commission analysis also shows that staff working in NHS sites with higher clinical research activity levels are [more likely](#) to recommend their own organisation.

Economic benefits

Clinical research represents a sound economic investment and investment in UK intellectual capital. **The NIHR Clinical Research Network supported clinical research activity [generated](#) £2.7 billion GVA in 2018/2019, with the estimated income for the NHS from life sciences companies totalling £355 million.**

For every patient recruited onto a commercial clinical trial between 2016 and 2018, the NHS in England [received](#) £9,189 from life sciences companies, and, where a trial drug replaced the standard of care treatment, saved £5,813.

Why does existing legislation fall short?

Health and Social Care Act 2012

Despite the well-recognised benefits that a research-active NHS delivers, current NHS legislation (the Health and Social Care Act 2012) does not mandate clinical research activity, stating only that there is a duty for CCGs (Clinical Commissioning Groups) to “promote” research. This same duty is proposed in current text of the Health and Care Bill. The NHS’s ability to prioritise the resourcing and delivery of research has been a major impediment to improving the UK’s clinical research environment over the last decade. **A clear legislative mandate is therefore needed.**

Current wording in the Bill

Clause 20, Page 17:

14Z40 Duty in respect of research

Each integrated care board must, in the exercise of its functions, promote—

(a) research on matters relevant to the health service, and

(b) the use in the health service of evidence obtained from research.

Because it is not mandatory, clinical research has in some cases been regarded as an optional extra, rather than a key part of routine patient care. **During the pandemic response, non-COVID clinical research has faced enormous disruption**, with studies paused or cancelled altogether, and key research staff [redeployed to support the frontline effort or prioritise COVID-19 studies](#). As we build back a more resilient health and care system, we should ensure that the ongoing provision of clinical research across all disease areas remains a priority and that there are the staff and resources in place to deliver this ambition alongside other critical health and care duties.

Levelling-up and addressing health inequalities

There is significant variability of opportunities for patients to engage in research, with disparities in participation reported for [geographic location](#), [socioeconomic background](#), [ethnic origin](#), and [across different disease areas](#). Traditionally, metropolitan hubs (often with teaching hospitals and an active engagement in clinical research delivery) can offer patients in their locality greater opportunity to enrol in clinical studies.

With clear evidence on the benefits to patient outcomes and the economy, **unequal distribution of research opportunities across the country is holding back both the levelling-up agenda, and our ability to address health inequalities.**

A legislative requirement, with improved accountability for ICS leadership teams, and a more inclusive research workforce, will play a key role in ensuring all patients have the opportunity to take part in clinical research, regardless of where they live, their gender or their ethnicity.

This would support the ambition set out in the Government's [Clinical Research Vision](#) to *“to make access and participation in research as easy as possible for everyone across the UK, including rural, diverse and under-served populations”*.

Why we must act now. An opportunity for change

COVID-19 has raised public awareness about the benefits of clinical research to unprecedented levels and has also increased the number of NHS staff engaging in research, with major studies such as RECOVERY providing research opportunities for new staff and previously inactive sites. **The Health and Care Bill provides a significant but time limited window of opportunity to embed these developments, enhance the UK's clinical research environment and deliver the Government's vision.**

Introducing a research requirement into the new NHS Integrated Care System structures will play a vital role in **embedding a 'research-active' culture across the NHS.**

It will also help to **ensure that ICS leadership teams are accountable** for providing patients and staff within NHS organisations for which they are responsible, with opportunities to engage with and participate in clinical research. ICSs are being established as the strategic system leaders for the NHS and its partner organisations to deliver integrated care and take a whole system approach. Research must be a core element of ICS regional plans if we are to maximise the strengths of the NHS and our world leading science capability for the benefit of patients.

While legislation is a critical element in delivering the Government’s ambition for UK Clinical Research, **it is important to stress that it must be accompanied by the necessary infrastructure (e.g. staffing levels and research capability, digital resources and tools, access to services), efficient trial approvals processes, the ability to reliably recruit patients, guidance, and dedicated staff time for research.**

It is important to recognise the current pressure NHS Staff and organisations are under following the COVID response, with a sizeable backlog of care and workforce fatigue. The evidence outlined in this brief shows that clinical research, rather than being a burdensome addition, can play a major role in our health system recovery which supports not only patient outcomes, but staff satisfaction also. However, to harness these benefits, it is imperative staff are supported to make the most of research opportunities. Addressing workforce shortages and promoting clinical academic careers will be a vital component of this. The research community is committed and able to work with NHSE/ICSs to co-create the necessary partnerships and ways of working to ensure all parts of the NHS can deliver clinical research.

For further information, please contact r.bundell@amrc.org.uk.

Additional resources:

- Academy of Medical Sciences: [Transforming health through innovation: Integrating the NHS and academia](#)
- AMRC: [Our vision for research in the NHS](#)
- ABPI: [Clinical Research Report](#)
- CRUK: [Creating Time for Research](#)
- NIHR: [Embedding a research culture](#)
- Royal College of Physicians: [Research for all: developing, delivering and driving better research](#)



Annex – full text of amendments on research

Amendment 79

Clause 20

- *Lord Sharkey, Lord Kakkar, Lord Patel, Baroness Blackwood*

Page 17, leave out lines 16 to 19 and insert—

“Each integrated care board must—

- (a) ensure that those eligible organisations for which the integrated care board is responsible conduct research on matters relevant to improving patient outcomes and health care delivery and promote the use in health and care of evidence obtained from research,
- (b) co-produce with place-based partnerships research aims to meet the needs of their local communities and ensure diversity of participation, and
- (c) transparently publish via their annual reports and joint forward plans the steps they have taken or plan to take to deliver clinical research.”

This amendment requires ICSs to ensure that eligible organisations for which the Integrated Care Board is responsible conduct research and requires ICSs to outline how they have, or plan to discharge such duties for research.

Amendment 81

Clause 20

- *Baroness McIntosh*

Page 17, line 19, at end insert—

“(2) Each integrated care board must each year prepare, consult on and adopt a research strategy for patient benefit which—

- (a) meets local need;
- (b) meets national research undertakings.

(3) In developing a strategy under subsection (2), an integrated care board must engage with—

- (a) the National Institute for Health Research, and
- (c) all relevant regional and national health and care research organisations.”

This amendment requires ICBs to outline how they have, or plan to discharge such duties for research.

Amendment 96

Clause 20

- *Baroness McIntosh*

Page 18, line 38, at end insert—

“14Z43A Duty on integrated care boards to consider requests to engage in clinical trials, and patient participation

(1) Each integrated care board must consider any request from the organiser of an authorised clinical trial for the integrated care board to engage in that trial.

(2) If such a request is accepted, the integrated care board must offer the ability to participate in the trial to any patient within their area who is eligible to take part.”

This amendment requires ICBs to conduct research by ensuring requests from organisers of authorised clinical trials are considered and patients are offered the ability to participate.

Amendment 196

After Clause 61

- *Lord Sharkey, Baroness Blackwood*

Insert the following new Clause—

“NHS Trusts and NHS Foundation Trusts research obligation

In schedule 4 of the National Health Service Act 2006 (NHS trusts established under section 25), omit paragraph 16 (research) and insert—

“16 NHS Trusts and NHS Foundation Trusts must—

- (a) must conduct research on matters relevant to improving patient outcomes and health care delivery and promote the use in health and care of evidence obtained from research,
- (b) must co-produce, with place-based partnerships, research aims that are intended to meet the needs of their local communities and ensure diversity of participation,
- (c) must transparently publish via their annual reports and joint forward plans the steps they have taken or plan to take to deliver clinical research, and
- (d) may make available staff and provide facilities for research by other persons.”

This amendment requires NHS Trusts and NHS Foundation Trusts to conduct research and requires them to outline how they have, or plan to deliver research.