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Chief Executives, NHS Trusts.
Chief Executives, Mental Health Trusts.
Chief Executives, Ambulance Trusts.
Chief Executives, Foundation Trusts.
Chief Executives, PCTs
Chief Executives, Strategic Health Authorities
Chief Executives, Special Health Authorities

Gateway no. 12153

Date: 9 July 2009

Dear Colleague

Requirements to support research in the NHS

We are writing to draw your attention to recent policy statements and operational requirements regarding research in the NHS. The key points are as follows. Further detail is provided in Annex A.

The **NHS Constitution** confirms:

- the commitment of the NHS *“to the promotion and conduct of research”*.

The **Handbook to the NHS Constitution** states:

- *“the NHS will do all it can to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them”*.

The **NHS Operating Framework** states:

- *“the NHS must play its full part in supporting health research”*;
- *“all providers of NHS care will need to increase their participation in research”*;
- *“the national ambition is to double the number of patients taking part in clinical trials and other well-designed research studies within five years”*; and
- *“SHAs are expected to ensure that NHS Trusts work with the National Institute for Health Research Comprehensive Clinical Research Network locally to contribute to this progressive increase”*.

The **Guidance for SHAs regarding their Duty to Promote Innovation** states that SHAs will report on:

- *“the actions the SHA has taken to support the work of the NIHR Clinical Research Networks locally and to develop the collaborative capacity of the NHS to join in research studies and trials.”*

The **Government Response to Review and Refresh of Bioscience 2015** states:

- *“Rather than asking each Trust to designate a Board member to take responsibility for research, the DH believes that it would be more effective for Trusts to set goals for research within their organisation and report on their achievement at least annually to the Board and in their annual report. The Department will be writing to the service shortly about this”;*
- *“The letter which the Department will be writing to the service will ask Trusts to set goals for research in their organisation”;*
- *“ The letter will ask Trusts to publish the average time it takes for the local research approval process to be completed”;*
- *“This letter will also ask Trusts to ensure that they use the NIHR Coordinated System for gaining NHS permission and that they do not develop unnecessary additional activities or bureaucracies locally.”*

We look forward to working with you to ensure that NHS is able to play its full part in harnessing the power of research to improve national health and increase national wealth.

Yours sincerely



Professor Dame Sally C Davies
Director General of Research and Development



David Flory
Director General of NHS Finance, Performance and Operation

Annex A

The following are the set of policy statements and formal requirements relating to research and the NHS which have been introduced over the last year.

The NHS Constitution

One of the “Principles that guide the NHS” states:

“The NHS aspires to the highest standards of excellence and professionalism - in the provision of high-quality care that is safe, effective and focused on patient experience; in the planning and delivery of the clinical and other services it provides; in the people it employs and the education, training and development they receive; in the leadership and management of its organisations; and through its commitment to innovation and to the promotion and conduct of research to improve the current and future health and care of the population.”

Subject to Parliamentary approval, all NHS bodies, and private and third-sector providers supplying NHS services in England will be required by law to take account of the Constitution in their decisions and actions. This legal duty is contained within the Health Bill, which was introduced into Parliament on 15 January 2009.

The NHS Constitution was published on 21 January 2009 and is available [here](#).

Handbook to the NHS Constitution

The “Rights and Pledges” for Informed Choice state:

“Research is a core part of the NHS. Research enables the NHS to improve the current and future health of the people it serves. The NHS will do all it can to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them. The NHS is therefore putting in place procedures to ensure that patients are notified of opportunities to join in relevant ethically approved research and will be free to choose whether they wish to do so.”

The Handbook to the NHS Constitution was published on 21 January 2009 and is available [here](#).

The Next Stage Review: High Quality Care for All

The Next Stage Review states:

“We will continue to transform health research in the NHS by implementing, consolidating and building on the Government’s strategy, Best Research for Best Health, for the benefit of patients and the public.”

The Next Stage Review was published on 30 June 2008 and is available [here](#).

The Operating Framework for the NHS in England 2009/10

The Operating Framework for the NHS states:

“High Quality Care for All made it clear that innovation must be central to the NHS if we are to improve constantly the quality of care. To achieve this, the NHS must play its full part in supporting health research. NHS trusts and NHS foundation trusts have a statutory duty to support education and training. All providers of NHS care will need to increase their participation in research. The national ambition is to double the number of patients taking part in clinical trials and other well-designed research studies within five years. SHAs are expected to ensure that NHS trusts work with the National Institute for Health Research Comprehensive Clinical Research Network locally to contribute to this progressive increase. In addition, from 31 December 2008 there will be a new duty on SHAs to promote innovation across their regions.”

The Operating Framework was published on 8 December 2008 and is available [here](#).

Quality Accounts

Subject to the successful passage of the current Health Bill (<http://services.parliament.uk/bills/2008-09/health.html>), all providers of NHS healthcare will be subject to a legal duty to publish Quality Accounts. The Bill gives the Secretary of State powers to make regulations setting out the content, format and timing of Quality Accounts, and to exempt certain classes of service or types of provider from the general duty, either permanently or temporarily. The Government's intention is that providers of acute care, including foundation, mental health and ambulance trusts, and larger private providers with NHS acute care contracts, will be subject to the duty from 1 April 2010, and that their first Quality Accounts will be published in June 2010, covering activity in 2009-10. Further details were set out in a “dear colleague” letter published on 23 April, Gateway no. 11733 (<http://www.monitor-nhsft.gov.uk/home/news-and-events/media-centre/latest-press-releases/new-reporting-requirements-put-quality-top-b>).

As indicated in the 23 April letter, the detailed mechanics of quality reporting are currently being tested by foundation trusts and by providers in NHS East of England. The evaluation of these tests will be used with the ongoing engagement work that started with High Quality Care for All to inform the development of a set of proposals on which the Government will consult over the summer and autumn.

The Government's current intention is that providers of NHS healthcare (ie. acute care in 2010) will be required to include in their Quality Accounts a measure showing: *“the number of patients recruited in the previous year to clinical research (i.e. research which has received Research Ethics Committee approval), expressed also as a percentage of the total number of patients treated”*.

Strategic Health Authorities' Duty to Promote Innovation

The new legal duty for SHAs to promote innovation has been made through Directions under Section 8 of the National Health Service Act 2006 which state: *"In performing its functions each Strategic Health Authority must promote innovation for the purpose of securing continuous improvement in the commissioning and provision of health care."*

The Guidance for SHAs regarding this legal duty states that SHAs will produce an Annual Innovation Report which sets out progress including:

"the actions the SHA has taken to support the work of the NIHR Clinical Research Networks locally and to develop the collaborative capacity of the NHS to join in research studies and trials."

The Guidance for SHAs was published on 27 April 2009 and is available [here](#).

Government Response to Review and Refresh of Bioscience 2015 Report

The Government response to the review and refresh of BIGT states:

"Quality Accounts offer a transparent way to ensure that Trusts report to their local populations on research activities, which are a key element of the quality of care. We will work with the NHS to ensure that providers who conduct research include in Quality Accounts the number of patients recruited in the previous year to clinical research (i.e. research which has received Research Ethics Committee approval). We will also explore other appropriate research indicators that link to the quality of care for inclusion in Quality Accounts, and/or other national reporting mechanisms."

The Department of Health (DH) Research Governance Framework for Health and Social Care (RGF) issued in 2005 requires providers of care to be aware of all research being undertaken within their organisation and ensure that it meets the standards set out in the RGF. Accountability lies with the Chief Executive who may delegate responsibility to a qualified and senior member of staff. Rather than asking each Trust to designate a Board member to take responsibility for research, the DH believes that it would be more effective for Trusts to set goals for research within their organisation and report on their achievement at least annually to the Board and in their annual report. The Department will be writing to the service shortly about this."

The objective contained within the Operating Framework is to double the number of patients taking part in clinical trials and other well-designed research studies within five years. We believe that the five year time-frame to deliver this is more realistic than three years."

As stated above we propose to include in the Quality Accounts a requirement for providers to report on the number of patients recruited in the previous year to


clinical research (i.e. research which has received Research Ethics Committee approval).

The letter which the Department will be writing to the service will ask Trusts to set goals for research in their organisation. The indicator in the Quality Accounts will require Trusts to report on the number of patients involved in clinical studies. The letter will ask Trusts to publish the average time it takes for the local research approval process to be completed.

This letter will also ask Trusts to ensure that they use the NIHR Coordinated System for gaining NHS permission and that they do not develop unnecessary additional activities or bureaucracies locally.”

The Government Response was published on 7 May 2009 and is available [here](#).

The above policy statements and formal requirements relating to research and the NHS can be summarised as:

Research and Innovation in the NHS		 Department of Health
The NHS	NHS Constitution	NHS commitment to the promotion and conduct of research
	NHS Operating Framework	NHS must play its full part in supporting research; National ambition to double the number of patients in clinical research
Strategic Health Authorities	NHS Operating Framework	SHAs to ensure that NHS trusts work with NIHR Clinical Research Network locally to contribute to the increased numbers of patients in clinical research
	Duty to Promote Innovation	SHAs to support NIHR Clinical Research Networks locally; SHAs to develop the capacity of the NHS to support research
Primary Care Trusts	NHS Providers	NHS Operating Framework
All providers to increase their participation in research		Quality Accounts
All providers to report on the number of patients in clinical research		Handbook to NHS Constitution
NHS Patients	The NHS will do all it can to ensure that patients are made aware of research that is of particular relevance to them	