

Embedding research into the health system

Build and support research throughout the NHS and public health system

We are a coalition of charities and organisations who fund and support health research in the UK. We share an interest in the changes proposed by the health and social care bill and the overarching reforms to the NHS and public health system.

We welcome the increased focus on research and innovation that followed the government's listening exercise, which provided a clear signal that the government wishes to foster a culture of research and innovation throughout the NHS and public health system.

The passage of the Health & Social Care Bill through the Lords offers us an opportunity to push for further clarity and commitments in key areas of concern for research, ensuring the new structures develop effective partnership with existing and newly created bodies.

The following briefing includes explanation and background information on the following amendments which we are supporting:

Duties of the Secretary of State towards research – Clause 5, Lord Willis and Baroness Morgan, Lord Patel and Lord Warner

Duties on NHS Commissioning Board to embed research throughout the health system –

Clause 20, Baroness Morgan and Lord Turnberg, TBC Clause 23, Lord Willis and Lord Turnberg

Duties on clinical commissioning groups towards research – Clause 23, Lord Willis

Abolition of the Health Protection Agency and the creation of Public Health England – Clause 53, Lord Patel

Establishment of the Health Research Authority – new clause, Lord Willis, Lord Patel, Lord Kakkar, Lord Warner

Background is also included on the following amendments which are relevant to research:

Approval functions of the Health Research Authority – new clause, Lord Willis, Lord Turnberg

Establishing a duty of co-operation between the Health Research Authority and the Medicines and Healthcare products Regulatory Agency – new clause, Lord Willis, Lord Turnberg

Establishing the National Research Governance Service as a component of the Health Research Authority – new clause, Lord Willis, Lord Turnberg

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Duties of the Secretary of State towards research

The bill introduces a duty towards research on the Secretary of State in clause 5

5The Secretary of State's duty as to research

After section 1C of the National Health Service Act 2006, insert—

“1Duty as to research

15“In exercising functions in relation to the health service, the Secretary of State must have regard to the need to promote—

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

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

A number of amendments have been tabled to probe the extent of this duty.

Supported amendment

Clause 5

LORD WILLIS OF KNARESBOROUGH

BARONESS MORGAN OF DREFELIN

Page 3, line 16, leave out “have regard to the need to”

Explanation: Clause 5 defines the Secretary of State's duty as to research. This amendment alters the Secretary of State's duty towards research from “have regard to the need to” promote research and the use of research evidence to simply “promote”.

Issues for debate: This probes the strength of the research duty on the Secretary of State, exploring how far “have regard to the need to promote” includes a requirement to act to promote research and the use of research evidence. This amendment provides an opportunity to call on the government to provide:

- **further clarification of the extent to which this duty requires the Secretary of State to act to promote research and the use of research evidence.**

Background: The duty on the Secretary of State to promote research and the use of research evidence needs to be clearly defined to ensure it leads to pro-active, top-down leadership and initiatives to embed research across the system. It should include requirements to take action to ensure research is embedded into the health system.

Supported amendment

Clause 5

LORD WILLIS OF KNARESBOROUGH

BARONESS MORGAN OF DREFELIN

Page 3, line 19, at end insert “, and

(c) research supported by the health service for the purpose of protecting the public in England from disease or other dangers to health.”

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Explanation: Clause 5 defines the Secretary of State's duty as to research. This amendment introduces further definition of the extent of this duty.

Clause 5

The Secretary of State's duty as to research. After section 1C of the National Health Service Act 2006, insert—

"1D Duty as to research.

*"In exercising functions in relation to the health service, the Secretary of State **must have regard to the need to promote—***

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

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

*(c) **research supported by the health service for the purpose of protecting the public in England from disease or other dangers to health.***

Issues for debate: This amendment seeks further definition of the research falling under (a) "research on matters relevant to the health service". This amendment provides an opportunity to call on the government to provide:

- **an explanation of how this research is captured by (a)**
- **further definition of (a) "research on matters relevant to the health service"**

Background: We would like to ensure the definition of research, which this duty requires the secretary of state to 'have regard to the need to promote', is broad enough to capture all health research.

Supported amendment

Clause 5

LORD WARNER

LORD PATEL

Page 3, line 17, after "service" insert

"(b) development of research findings for clinical application in the health service, including the necessary informatics skills and technology support" and in next line substitute "(c)" for "(b)"

Explanation: Clause 5 defines the Secretary of State's duty as to research. This amendment introduces further definition of the extent of this duty, explicitly introducing a responsibility on the Secretary of State to promote the development of research findings for clinical application in the health service.

Issues for debate: This amendment seeks further definition of the extent of the Secretary of State's duty to research, specifically probing whether this includes a direct responsibility on the Secretary of State to ensure that research findings are used to support the development of clinical applications in the health service and that the necessary informatics skills and technology required to support this is developed. This amendment provides an opportunity to call on the government to provide:

- **a commitment to introduce arrangements to develop research findings for clinical application in the health service, or**
- **clarity that this is captured within the clause as it stands**

Background: As one of the largest single healthcare systems in the world, the NHS should offer the UK a unique strategic advantage as a resource for medical research and innovation. However in practice the

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adoption and spread of new innovations within the NHS is often very slow and sometimes even the best of them fail to achieve widespread use. The NHS Chief Executive Innovation Review is currently exploring how we can accelerate the adoption and diffusion of innovations in the NHS.

Strong leadership by the Secretary of State to ensure the development of informatics skills and technology and drive the development of an environment where research findings are taken up to support the development of clinical applications will be vital to integrate innovation into the fabric of the NHS, allowing the best care to be quickly provided to patients, delivering more cost-effective health services and attracting commercial investment and R&D into the UK.

Supported amendment

Clause 5
LORD WARNER
LORD PATEL

Page 3, line 19, at end insert—

“() In discharging his duty under this section the Secretary of State shall ensure robust arrangements for safeguarding the funding of research and its application to health services.”

Explanation: Clause 5 defines the Secretary of State’s duty as to research. This amendment introduces an explicit responsibility on the Secretary of State to safeguard the funding of research and its application to health services.

Issues for debate: This amendment seeks further definition of the extent of the Secretary of State’s duty to research. This amendment provides an opportunity to call on the government to provide:

- **a commitment to introduce robust arrangements for safeguarding the funding of research and its application to health services, or**
- **clarity that this responsibility is captured within the clause as it stands**
- **a commitment to the ongoing safeguarding of research funding in the NHS**

Background: The government currently invests approximately £1 billion per annum on clinical research in the NHS via the National Institute of Health Research (NIHR). This funds both research projects and provides the infrastructure to support research financed by external funders including medical research charities. We are seeking a clear indication from the government that they are committed to continuing this funding.

In their response to the NHS Future Forum the government committed to make sure that clinical commissioning groups and the NHS Commissioning Board ensure that treatment costs for patients who are taking part in research funded by government and research charity partner organisations are funded through normal arrangements for commissioning patient care, as set out in existing guidance. These are currently distributed by PCTs but the Department of Health has no power of enforcement to ensure these are paid. We are concerned about the lack of clarity over how the bodies within the new structure of the NHS will take responsibility for covering these excess treatment costs (ETCs).

Duties on NHS Commissioning Board to embed research throughout the health system

Supported amendment

Clause 20
BARONESS MORGAN
LORD TURNBERG

page 18, line 34, leave out “have regard to the need to”

Explanation: Clause 20 defines the NHS Commissioning Board’s duty as to research. This amendment alters the NHS Commissioning Board’s duty towards research from “have regard to the need to” promote research and the use of research evidence to simply “promote”.

Issues for debate: In response to the NHS Future Forum, the government committed to ensure a culture of research and innovation is embedded in the arrangements for the NHS Commissioning Board. This amendment probes the strength of the research duty on the NHS Commissioning Board, exploring how far “have regard to the need to promote” includes a requirement to act to promote research and the use of research evidence. This amendment provides an opportunity to call on the government to provide:

- **further clarification of the extent to which this duty requires the NHS Commissioning Board to act to promote research and the use of research evidence.**

Background: It is essential that the changes to structures and culture needed to promote research and innovation are built into the new health system as it is developed. To deliver this, the NHS Commissioning Board must provide clear leadership in research and innovation and the use of research evidence.

Supported amendment

Clause 20
BARONESS MORGAN
LORD TURNBERG

*Clause 20, page 18, line 37, at end insert “, and
(c) research supported by the health service for the purpose of protecting the public in England from disease or other dangers to health”*

Explanation: Clause 20 defines the NHS Commissioning Board’s duty as to research. This amendment introduces further definition of the extent of this duty.

Issues for debate: This amendment seeks further definition of the research falling under (a) “research on matters relevant to the health service” which the NHS Commissioning Board will have a duty to promote. This amendment provides an opportunity to call on the government to provide:

- **an explanation of how research for the purpose of protecting the public in England from disease or other dangers to health is captured by (a)**
- **further definition of (a) “research on matters relevant to the health service”**

Background: It is essential that the changes to structures and culture needed to promote research and innovation are built into the new health system as it is developed. Leadership from the NHS Commissioning Board will ensure we can deliver this. We would like to ensure the definition of research in the duty placed on the NHS Commissioning Board is broad enough to capture all health research, ensuring they are required to provide leadership across health research.

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Supported amendment

Clause 20
BARONESS MORGAN
LORD TURNBERG

page 21, line 22, after "13E" insert "13L"

Explanation: Clause 20 defines the NHS Commissioning Board's duty as to research. This amendment introduces a requirement for the Board to include detail of how it plans to discharge its duties in regard to research in its annual business plan.

Issues for debate: The NHS Commissioning Board is required to include detail of how it plans to discharge its duties in regard to Public involvement and consultation by the Board and improvement in quality of services in its annual business plan. This amendment provides an opportunity to call on the government to provide:

- **a commitment that the Board should provide similar detail on how it plans to discharge its duties in regard to research.**

Background: Before the start of each financial year, the NHS Commissioning Board must publish a business plan setting out how it proposes to exercise its functions in that year and each of the next two financial years. Requiring the board to include delivery of their duty in regard to research in this annual business plan will ensure plans are made for delivery of these duties.

Supported amendment

Clause 20
BARONESS MORGAN
LORD TURNBERG

page 21, line 38 after "13E" insert "13L"

Explanation: Clause 20 defines the NHS Commissioning Board's duty as to research. This amendment introduces a requirement for the Board to include an assessment of how well it has discharged its duties in regard to research in its annual report

Issues for debate: The NHS Commissioning Board is required to include an assessment of how well it has discharged its duties in regard to Public involvement and consultation by the Board and improvement in quality of services in its annual business plan. This amendment provides an opportunity to call on the government to provide:

- **a commitment that the Board should provide similar detail on how well it has discharged its duties in regard to research.**

Background: As soon as practicable after the end of each financial year, the Board must publish an annual report on how it has exercised its functions during the year. Requiring the board to include an assessment of how well it has discharged its duty in regard to research in this annual report will ensure its performance is monitored.

Supported amendment

Clause 23

LORD WILLIS OF KNARESBOROUGH

BARONESS MORGAN OF DREFELIN

LORD PATEL

LORD TURNBERG

Page 44, line 24, after “14V” insert “, 14X”

Explanation: This amendment would commit the NHS Commissioning Board to giving particular attention in its performance assessment of clinical commissioning groups (CCGs) to how each one is fulfilling its duty in respect of research.

Issues for debate: In their response to the NHS Future Forum the government committed to creating a new duty for clinical commissioning groups to promote research and innovation and the use of research evidence. They also committed to ensure a culture of research and innovation is embedded in the arrangements for the board. They are yet to provide detail on how the NHS Commissioning Board will assess the performance of CCGs in promoting research and innovation and the use of research evidence. This amendment provides an opportunity to call on the government to provide:

- **further detail on how the NHS Commissioning Board will embed a culture of research and innovation throughout the health system including:**
 - **how the NHS Commissioning Board will assess the use of research evidence in the commissioning of services by clinical commissioning groups**
 - **how the NHS Commissioning Board will assess the performance of clinical commissioning groups in promoting research and innovation and supporting clinical research**

Background: We welcome the duties in respect of research for both the NHS Commissioning Board and the CCGs. To ensure a research-friendly culture flourishes across the NHS, we would like to find out how the NHS Commissioning Board will work with CCGs to encourage and promote research.

The NHS Commissioning Board will need to conduct a performance assessment of each CCG. In this assessment, the legislation commits the Board to give particular attention to the CCGs' duties to secure continuous improvement in the quality of services, obtain appropriate advice and involve the public. We would like to see the NHS Commissioning Board give a similar level of attention to the CCGs' duty in respect of research.

Each financial year the NHS Commissioning Board will publish a summary report of the performance of CCGs. This is an ideal opportunity for the NHS Commissioning Board to communicate how research is being embedded across CCGs and how the Board is working with CCGs who may need support in realising this vision.

Duties on clinical commissioning groups towards research

The bill introduces a duty towards research on clinical commissioning groups in clause 23. In their response to the NHS Future Forum the government committed to creating a new duty for clinical commissioning groups to promote research and innovation and the use of research evidence.

Supported amendment

Clause 23

LORD WILLIS OF KNARESBOROUGH

BARONESS MORGAN OF DREFELIN

LORD PATEL

LORD TURNBERG

Page 41, line 41, after "14Q" insert " 14X"

Explanation: This amendment would commit each clinical commissioning group (CCG) to providing details in its commissioning plan about how it is using and promoting research when commissioning services.

Issues for debate: In their response to the NHS Future Forum the government committed to creating a new duty for clinical commissioning groups to promote research and innovation and the use of research evidence. They are yet to provide detail on how CCGs will embed evidence based commissioning of services throughout the system and how they will support clinical research. This amendment provides an opportunity to call on the government to provide:

- **further detail on how clinical commissioning groups will be expected to embed the use of research evidence in the commissioning of services throughout the system**
- **further detail on how clinical commissioning groups will fulfil their duty in respect of research and innovation when drawing up their commissioning plan and in particular how they will support clinical research.**

Background: Medical research in the UK is a success story: the UK has created nearly a quarter of the world's top 100 medicines. But there are challenges: the UK's global market share of clinical trials has dropped from 6% in 2000 to 2-3% in 2006.

Following on from the Academy of Medical Science's review into health regulation and governance, it is crucial that more is done to streamline clinical regulation and ensure duplication of activities does not occur when setting up trials. It is also crucial that more clarity is given about how "excess treatment costs" to support charity funded research on the NHS will be distributed (it was previously distributed via PCTs commissioning budgets). We are concerned that CCGs receive the necessary support to establish, coordinate and develop expertise, forging links with established research collaborations so that they can engage meaningfully with research.

Each CCG must draw up and publish a Commissioning Plan. We would like each CCG to consider how it will fulfil its duty in respect of research when drawing up its commissioning plan and in particular how it will support clinical research. This issue is especially important for clinical trials for cancer: three quarters of all cancer patients involved in clinical research are on a Cancer Research UK funded trial. In 2009-10 over 3000 clinical studies were conducted in the NHS; 37 per cent were funded by AMRC member charities.

As part of their duty in respect of research, CCGs will also be expected to consider the available evidence base when carrying out its functions. This is an ideal opportunity for the Government to confirm how it will embed the use of research evidence in the commissioning of services throughout the system.

Abolition of Health Protection Agency and the creation of Public Health England

Supported amendment

Clause 53
LORD WARNER
LORD PATEL

Page 84, line 15, at end insert—

“() On the abolition of the Health Protection Agency, the Secretary of State will allocate their functions and any others he considers appropriate to an Executive Agency with its own chief executive as accounting officer within the Department and with a management board with at least three non-Executive Directors with expertise in its functions selected by the Department’s Chief Scientific Adviser.”

Explanation: This amendment inserts a clause to ensure that the current functions of the Health Protection Agency are taken on in an Executive Agency (Public Health England) with a board that includes non-executive directors.

Issues for debate: The Government has not yet provided details on the governance arrangements for Public Health England (PHE), which will be established as an Executive Agency. This amendment provides an opportunity to call on the government to provide:

- **a commitment that PHE’s independence through its status as an Executive Agency status will be reinforced by a Board with independent non-executive members and Chair.**

Background: An essential requirement of the public health system is that it can provide the Government and the public with independent advice on health protection issues, including appropriate emergency responses. This function is currently provided by the Health Protection Agency (HPA) and under the current proposals, these functions of the HPA will be brought into PHE. It is therefore important that PHE has a distinct identity from the Department of Health to maintain the ability of the system to provide independent advice - either perceived or actual - on what, at times, will include contentious issues.

Following the listening exercise the Government acknowledged that the current functions of HPA should retain independence from the Department of Health following the reforms and has committed to establishing Public Health England as an Executive Agency. We welcome this development, but it is important that this Executive Agency status is reinforced by suitable governance arrangements. For example, visibly independent non-executive Board members and Chair, could provide further reassurance that PHE is independent and would speak out on behalf of the public’s health whenever necessary.

Establishing the health research authority in primary legislation

Supported amendment

LORD WILLIS OF KNARESBOROUGH

LORD PATEL

LORD KAKKAR

LORD WARNER

Insert the following new Clause—

“The Health Research Authority

- (1) There shall be a body corporate called the Health Research Authority (referred to as “the HRA”).*
- (2) The Secretary of State shall make all necessary regulations to establish the HRA within 12 months of the Act receiving Royal Assent.*
- (3) The HRA shall manage a co-ordinated process for all aspects of the approval of health research involving human participants or their data, including—*
 - (a) the provision of ethics committee opinions and other approvals,*
 - (b) with the National Institute for Health Research and NHS Trusts, delivering a consistent, efficient process for obtaining permission for research carried out under the scope of the Research Governance Framework for Health and Social Care (referred to as “NHS R&D permissions”),*
 - (c) with the Medicines and Healthcare Products Regulatory Authority, improving the regulation of clinical trials of medicinal products, and*
 - (d) other such functions as may be specified in regulations including those currently being undertaken by organisations which will cease to function following the implementation of future legislation.*
- (4) The HRA shall have the following general functions—*
 - (a) providing general oversight and guidance as it considers appropriate in relation to activities within its remit,*
 - (b) publishing annual metrics and indicators on all research approvals within its remit,*
 - (c) working with relevant bodies across England, Wales, Scotland and Northern Ireland to address differences in practice and legislation, and providing supporting guidance or codes of practice that apply across the UK,*
 - (d) superintending compliance with requirements imposed by legislation relevant to its remit,*
 - (e) monitoring developments relating to activities within its remit, and*
 - (f) facilitating and promoting health research involving human participants or their data.*

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(5) *The HRA must carry out its functions effectively, efficiently and economically.*

(6) *In carrying out its functions, the HRA must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).*

(7) *The Special Health Authority known as the Health Research Agency is abolished and its functions transferred to the HRA.”*

Explanation: This amendment is a new clause designed to probe the Government’s intentions for the establishment of the Health Research Authority (HRA) as a non-departmental public body (NDPB).

The amendment would establish the HRA as a NDPB and sets out the HRA’s role in coordinating the approval and regulation of health research involving human participants or their data. This includes: **ethics committee opinions and other specialist approvals**; working with NHS Trusts on **NHS R&D permissions**; and working with the Medicines and Healthcare products Regulatory Agency on **clinical trials of medicinal products**.

The HRA would also fulfil other key functions in relation to the regulation and governance of health research, including **producing authoritative guidance** on requirements; **publishing annual metrics** on research approvals; and **working with counterparts in the devolved administrations to streamline the UK-wide environment**.

Aim of the discussion: The existing regulation and governance pathway has developed in a piecemeal manner resulting in a fragmented approval process, characterised by unnecessary process steps and complexity. The HRA needs to be created in a way that achieves a single streamlined, coordinated pathway. We now call on the Government to provide:

- **a comprehensive vision of the future functions of the HRA and the regulatory and governance framework as a whole;**
- **a timetable for the creation of the HRA in primary legislation;**
- **clarity on how the HRA will deliver coordination and oversight across a single regulatory and governance pathway.**

Background: There is evidence that health research activities are being seriously undermined by an overly complex regulatory and governance environment. This threatens the ability of researchers to meet the expectations and aspirations of the public in developing new interventions to benefit patients. The barrier posed by the regulatory and governance environment is evidenced by a fall in the UK’s global share of patients in clinical trials, and by the increased time and costs of navigating the UK’s complex research approval processes. As a specific example, a recent analysis from Cancer Research UK showed that after its funding for a study has been agreed, it now takes an average of 621 days to recruit the first patient. In short, the current situation is stifling research and driving medical science overseas.

In January 2011, the Academy of Medical Sciences (AMS) outlined a series of steps to streamline the regulation and governance of health research¹. These recommendations were informed by over 300 evidence submissions and have received strong support from across the research community and all political parties. The Academy recommended creating a single research regulator to:

- **Manage a single coordinated pathway** for the regulation and governance of all health research. This would align the current process of obtaining permission for research within the NHS

¹A new pathway for the regulation and governance of health research (2011)
<http://www.acmedsci.ac.uk/index.php?pid=99&puid=209>

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(“NHS R&D Permissions”), identified as the major bottleneck in the current pathway, with all other approvals (e.g. ethics) and authorisations.

- **Reduce complexity, timelines, costs and inefficiencies.**
- **Build and maintain confidence in the conduct and value of health research** through independence, transparency, accountability and consistency.

The Government has laid Statutory Instruments before Parliament to create the Health Research Authority (HRA) in secondary legislation and has also committed to establishing the HRA in primary legislation in a second Health and Social Care Bill in the next session, subject to securing parliamentary time.

While this response is welcomed, further detail is needed on how the Government plans to implement the vision set out in the Academy’s report and the role that the HRA will play in this.

The Government has responded to the Academy’s recommendations by introducing plans that make future funding conditional on NHS Trusts meeting new approval timelines. While we welcome this step forward, it remains unclear how this NHS R&D permissions process will be aligned with the functions of the HRA and how the complexity and duplication in the NHS R&D permissions process will be reduced.

Approval functions of the Health Research Authority

Background information

NEW CLAUSE
LORD WILLIS
LORD TURNBERG

Insert the following new Clause—

“The Health Research Authority: approval functions

(1) The following functions are transferred to the Health Research Authority—

- (a) advising the Secretary of State on applications for support to process confidential patient information under section 251 of the NHS Act 2006,*
- (b) functions of the Human Tissue Authority in relation to the scheduled purpose of research in connection with disorders, or the functioning, of the human body,*
- (c) functions of the Human Fertilisation and Embryology Authority in relation to the provision of licences for research, and*
- (d) advising Health Ministers on the certification of doctors and dentists wishing to administer radioactive medicinal products to humans for research under the Medicines (Administration of Radioactive Substances) Regulations 1978.”*

Explanation: This probing amendment is a new clause that sets out the specific health research approvals functions of the HRA.

A new clause (set out above) would establish the HRA as a non-departmental public body and transfers the current functions of the National Research Ethics Service to this new body. **This additional amendment would transfer the research functions of the following organisations to the HRA:**

- The **Ethics and Confidentiality Committee** (ECC) of the National Information Governance Board. The ECC advises the Secretary of State on the use of certain types of patient information in research. The ECC’s role includes assessing whether a research project fulfils the criteria to be exempt from the common law of confidentiality, under section 251 of the NHS Act 2006, to enable patient data from which individuals can be identified to be used in research without consent.
- The **Human Tissue Authority** (HTA), which regulates the use of human tissue in research under the Human Tissue Act 2004.
- The **Human Fertilisation and Embryology Authority** (HFEA), which regulates the use of human embryos in research under the Human Fertilisation and Embryology Act 1990.
- The **Administration of Radioactive Substances Advisory Committee** (ARSAC), which regulates the use of radioactive medicinal products.

Issues for debate: The Government has not yet set out full proposal for its plans for the HRA. This amendment provides a useful opportunity to seek from Government:

- **clarity around their proposals for which approval functions should be transferred to the HRA.**

Background: The UK's regulatory and governance pathway for health research is extremely complex and has developed in an *ad hoc* manner, with a large number of bodies responsible for different aspects of approvals. These multiple layers of regulation and governance lead to duplication and overlap in roles and responsibilities and uncertainty in the interpretation of requirements. The Academy of Medical Sciences (AMS) report *A new pathway for the regulation and governance of health research*², informed by over 300 evidence submissions, identified a real need for this complexity to be reduced.

In response to the Academy's report, in the *Plan for Growth*³ in March 2011 the Government said "it is far too difficult to navigate the complex national and local processes for research approvals. At national level, the Government will create a health research regulatory agency to combine and streamline the approvals for health research which are at present scattered across many organisations." The Government has progressed plans to establish the HRA as a Special Health Authority. However, although this will house the National Research Ethics Service, no further details have been provided on the longer-term goal of using the HRA to streamline the landscape, for example, on which functions will be included in its remit.

The Government has said that it will consult on the future of the functions of the HTA and HFEA in the autumn. In addition, during the passage of the Public Bodies Bill through the House of Lords, Earl Howe committed to not transfer any functions of the HFEA or HTA to the HRA until it has been established as a non-departmental public body in primary legislation.

Establishing a duty of co-operation between the Health Research Authority and the Medicines and Healthcare products Regulatory Agency

Background information

NEW CLAUSE
LORD WILLIS
LORD TURNBERG

Insert the following new Clause—

"The Health Research Authority: Duty of co-operation with MHRA

(1) The Health Research Authority and the Medicines and Healthcare products Regulatory Agency must co-operate with each other in the exercise of their respective functions to develop a co-ordinated process for the approval of clinical trials of medicinal products and to deliver improvements to the regulation of these trials."

Explanation: This probing amendment is a new clause that would establish a duty of co-operation between the HRA and the Medicines and Healthcare products Regulatory Agency (MHRA).

Issues for debate: It is expected that the new Health Research Authority (HRA) will take on most aspects of the regulation of health research, except for the regulation of clinical trials of investigational medicinal products and advanced therapy medicinal products, which will continue to be regulated by the MHRA. The

²A new pathway for the regulation and governance of health research (2011)

<http://www.acmedsci.ac.uk/index.php?pid=99&puid=209>

³Plan for Growth (2011)

http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf

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HRA is not currently expected to take on governance functions, further information on this topic is provided below in relation to the National Research Governance Service. This amendment provides a useful opportunity to seek from Government:

- **clarity around their expectations for the relationship between the HRA and MHRA;**
- **an explanation of what steps the Government is taking to influence the revision of the Clinical Trials Directive in order to improve the regulatory environment for clinical trials in the UK.**

Background: The UK's global share of patients in clinical trials fell from 6 per cent to 2-3 per cent between 2000 and 2006. This fall is, in part, attributed to the time and cost burdens of navigating the UK's complex research approval processes. Clinical trials of investigational medicinal products are regulated by the MHRA under the European Clinical Trials Directive.

The Academy of Medical Sciences report *A new pathway for the regulation and governance of health research*⁴, informed by over 300 evidence submissions, called for MHRA to work closely with the new HRA to enable a seamless approach to the regulation and governance of health research.

In the *Plan for Growth*⁵ the Government said "the new agency will work closely with the Medicines and Healthcare products Regulatory Agency to create a unified approval process and promote proportionate standards for compliance and inspection within a consistent national system of research governance." No further information has been provided on how this relationship is expected to work in practice or how a unified process will be achieved, for example how the bodies will share information and how accountability will be ensured.

The EU Clinical Trials Directive has created a number of difficulties for clinical trials in the UK. The Directive adopts a 'one size fits all' approach to clinical trials of investigational medicinal products where the same regulatory requirements are imposed on trials of drugs that have been used extensively in the past, such as aspirin, as first-in-human studies of a brand new drug. This imposes an unnecessary burden on trials of established products, without providing greater protection for trial participants. This has caused delays to, and may have prevented, trials that were designed to improve treatment options for patients. The Directive is currently under review by the European Commission and a revised draft of the Directive is expected to be put to the European Parliament in 2012. In the *Plan for Growth*⁵ the Government also commit-

Establishing the National Research Governance Service as a component of the Health Research Authority

Background information

*NEW CLAUSE
LORD WILLIS
LORD TURNBERG*

Insert the following new Clause—

"The Health Research Authority: National Research Governance Service

(1)A component of the Health Research Authority, known as the National Research Governance

⁴A new pathway for the regulation and governance of health research (2011)

<http://www.acmedsci.ac.uk/index.php?pid=99&puid=209>

⁵Plan for Growth (2011)

http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf

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Service, shall lead a streamlined common service for obtaining permission for research carried out under the scope of the Research Governance Framework for Health and Social Care (referred to as “NHS R&D permissions”).

(2)The National Research Governance Service will have the following general functions—

- (a) undertaking all study-wide NHS research governance checks, ensuring consistent national standards,*
- (b) recommending research projects as suitable for undertaking in the NHS, subject to local assessment of feasibility and delivery by NHS Trusts,*
- (c) managing the process requiring NHS Trusts to determine local feasibility within 20 working days,*
- (d) maintaining records on NHS staff to confirm their competence to conduct research, and*
- (e) providing in relation to activities within its remit general oversight and guidance as it considers appropriate.*

(3)The National Research Governance Service and NHS Trusts must have regard to the National Institute of Health Research’s Research Support Services standard procedures, framework of good practice and benchmarks for performance.”

Explanation: This probing amendment is a new clause that would establish a component of the HRA called the National Research Governance Service (NRGS).

The NRGS would lead a streamlined common service for obtaining permission to perform research at NHS sites. The functions of the NRGS would include: undertaking **all ‘study-wide’ governance checks** that are independent of the specific research site; making a **recommendation on whether the study is fit for undertaking within the NHS**; **coordinating local assessments of feasibility** at NHS Trusts.

Issues for debate: NHS R&D permissions are currently the greatest regulatory and governance barrier to health research. Some have expressed concern that the Government’s current proposals may not be sufficient to address these serious difficulties. This amendment provides a useful opportunity to seek from Government:

- **clarity on the expected role of the Health Research Authority with respect to NHS R&D permissions;**
- **detail on how steps will be taken to reduce complexity and duplication in the NHS R&D permissions process.**

Background: Before health research takes place in the NHS, permission is needed from each NHS site where the research is going to take place. These are known as “NHS R&D permissions”. For multi-site studies, such as some clinical trials, this means researchers must apply to every individual NHS Trust that they would like to involve; in some cases this will be over 100 different sites.

*The Research Governance Framework for Health and Social Care*⁷ requires NHS Trusts to grant NHS R&D permission for each research study. Since each Trust applies its own interpretation of these requirements, there are vast inconsistencies between Trusts. In addition, in many cases each Trust undertakes its own checks, rather than sharing these where possible, leading to extensive duplication across the system. Each

⁷The Research Governance Framework for Health and Social Care
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

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Trust is an independent legal entity and this is sometimes given as a reason that Trusts cannot delegate responsibility for aspects of the NHS R&D permissions process. However, some groups of Trusts have worked together to reduce duplication by sharing the results of each others' checks.

The Academy of Medical Sciences report *A new pathway for the regulation and governance of health research*⁸, informed by over 300 evidence submissions, identified NHS R&D permissions as the single greatest barrier to health research and the rate-limiting step in some studies. The Academy recommended increasing the speed of NHS R&D permissions by creating a National Research Governance System to lead a single, consistent, efficient system for the NHS as a whole.

In the *Plan for Growth*⁹ the Government responded to the Academy's recommendations by introducing plans to improve the current NHS R&D permission process by introducing standard operating procedures and making future funding conditional on NHS Trusts meeting new approval timelines. These changes are welcome, but it remains unclear whether these steps will be sufficient to make the necessary improvements to this process. Furthermore, no detail has been provided on the how the NHS R&D permissions process will be aligned with the functions of the HRA.

⁸A new pathway for the regulation and governance of health research (2011)
<http://www.acmedsci.ac.uk/index.php?pid=99&puid=209>

⁹Plan for Growth (2011)
http://cdn.hm-treasury.gov.uk/2011budget_growth.pdf