

Title: Health Research Authority (HRA) IA No: 9517 Lead department or agency: Department of Health Other departments or agencies:	Impact Assessment (IA)
	Date: 03/07/2012
	Stage: Final
	Source of intervention: Domestic
	Type of measure: Primary legislation
Contact for enquiries:	

Summary: Intervention and Options	RPC Opinion: GREEN
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Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Measure qualifies as One-Out?
£3.721m	£0m	£0m	No
			NA

What is the problem under consideration? Why is government intervention necessary?

The complexity of health research regulation and governance has increased over the last 20 years. The Academy of Medical Sciences (AMS) review of regulation and governance in health research said that this complexity is impacting on health research undertaken in the UK. To address this quickly, the HRA was established as a Special Health Authority (SpHA) on 1 December 2011. Whilst the problems of complexity and bureaucracy in regulation are being addressed by the SpHA, it still lacks independence and stability which are essential to its purpose of protecting and promoting the interests of participants and the public in research. Government intervention is necessary to establish the HRA as a NDPB.

What are the policy objectives and the intended effects?

The objectives are to establish HRA as part of a stable health and social care system, as an independent regulator with an overarching objective to protect and promote interests of participants and the public in research. Intended effects are to: (a) put HRA at arm's-length of Ministers on a stable, independent footing assured by parliamentary scrutiny; (b) give HRA a stronger basis to promote a consistent system across health and social care and the UK; (c) strengthen public confidence in the protection regulation provides; (d) give HRA independence so it can put interests of research participants and the public first and be seen to be free from political interference; and (e) provide stability for researchers and funders including industry.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Two options have been considered. Option 0 - Do nothing. Retain the HRA as a SpHA. The AMS report recommended establishing the HRA as an arm's-length body but in order to ensure that problems are addressed quickly, it recommended establishing it as a SpHA in the interim.

Option 1 - Establish the HRA as a NDPB. The AMS supported this option.

Option 1 is the preferred option as it would put the HRA at arm's-length of Government enabling it to act independently in the interests of participants and potential participants and the public, and be seen to be free from political interference. The stability will assure industry that the HRA will continue to make research easier to undertake through robust, proportionate regulation and provide a stronger basis for the HRA to promote a consistent system of regulating research across health and social care and across the UK.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: Month/Year					
Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro No	< 20 No	Small No	Medium No	Large No
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/A	Non-traded: N/A	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister:  Date: 3/7/12

Summary: Analysis & Evidence

Policy Option 1

Description: Option 1 - Establish the HRA as a NDPB

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 3.721

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0.01	0.014	3.721

Description and scale of key monetised costs by 'main affected groups'

Transition costs include recruitment costs of up to 2 non-executive directors (£10,000).
Annual costs includes paying salaries of up to 2 non-executive directors (£14,000 pa).

Other key non-monetised costs by 'main affected groups'

There are costs associated with reconfiguration of Information Technology, estates, corporate functions and other indirect costs in establishing the HRA as a SpHA. However, it is anticipated that no additional costs will be incurred in establishing HRA as a NDPB and even if there were some unanticipated costs, these costs are expected to be very low.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate			

Description and scale of key monetised benefits by 'main affected groups'

It is difficult to monetise the benefits associated with the greater independence and stability associated with establishing the HRA as a NDPB. Hence for the purpose of this Impact Assessment, the benefits are kept as qualitative benefits.

Other key non-monetised benefits by 'main affected groups'

The increased assurance for participants and potential participants and the public that research is safe and that they are protected from unethical research is expected to deliver positive benefits through increased participation in research. The stable platform that NDPB status will provide for funders of research is expected to deliver positive benefits of increased research being undertaken in the UK providing increased opportunities for people to participate in research.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

In the absence of detailed cost information, estimates of costs are based on the assumption that the transition from SpHA to NDPB will be relatively seamless. The Department envisages that there will be no reorganisation as the functions that the HRA undertakes will remain the same. There is a risk therefore that the costs could be underestimated but given the size of the organisation, this is unlikely to be significant.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:	In scope of OIOO?	Measure qualifies as
Costs: 0	No	NA
Benefits: 0		
Net: 0		

Evidence Base (for summary sheets)

Economic context / history to the problem under consideration

1. The complexity of health research regulation and governance has increased over the last 20 years through successive legislative changes. The Academy of Medical Sciences (AMS) review of regulation and governance in health research which reported in January 2011 said that this complexity is impacting on health research undertaken in the UK. To address the problems quickly, the Health Research Authority (HRA) was established as a Special Health Authority (SpHA) on 1 December 2011. Whilst the problems of complexity and bureaucracy in regulation are being addressed by the HRA as a SpHA, it still lacks independence and stability which are essential to the HRA's purpose of protecting and promoting the interests of participants and potential participants and the public in research. Government intervention is necessary to establish the HRA as a Non Departmental Public Body (NDPB).
2. The White Paper, *Equity and excellence: Liberating the NHS*, committed to cutting bureaucracy and improving efficiency. The arm's-length bodies review set out the Department's proposals to abolish arm's-length bodies (ALBs) that do not need to exist, streamline the functions of those that do and transfer the functions of those that can be better delivered by other organisations. The review set out the Department of Health's intention to create a new research regulator which will co-operate with various bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA) for the purposes of creating a unified approval process for health research and promoting consistent and proportionate standards for compliance and inspection as part of plans to simplify the regulatory landscape.
3. To inform the establishment of the new research regulator, the Department of Health asked the AMS to undertake a review of regulation and governance of health research. The AMS found that new requirements and checks have been introduced to address particular issues, but these sit on top of existing functions thereby increasing bureaucracy for researchers meaning it is slow and more costly to get research projects up and running.
4. In 2011 the AMS report *A new pathway for the regulation and governance of health research* (2011) cited the Bioscience Innovation and Growth Team's 2009 *Review and refresh of bioscience 2015* stating that in 2002, 46 percent of EU products in clinical trials were being developed in the UK; by 2007 this had fallen to 24 percent. Furthermore, citing Kinapse *Commercial Clinical Research in the UK: A Report for the Ministerial Industry Strategy Group Clinical Research Working Group* (2008), the AMS report also stated that while data from the MHRA showed that the number of trials approved has stayed constant between 2004 and 2008, our global market share of patients in trials has dropped from 6 percent to 2 to 3 percent. The AMS report quoted the ABPI in saying that almost half of the representatives of major pharmaceutical industries surveyed in 2008 indicated that they expected to reduce the number of clinical trials in the UK. The AMS report concluded that the current situation is stifling research and driving medical science overseas.
5. Economic growth is clearly a key priority for the UK. The life sciences industry, which includes pharmaceutical companies as well as biotechnology and medical technology organisations, is a substantial player in the UK economy and the UK is competing to attract industry in a global market. A thriving life sciences industry is also critical to the ability of the NHS to deliver world-class outcomes. Research is vital in providing the new knowledge needed to improve health outcomes and reduce inequalities and research active organisations are better at adopting research evidence into practice. Addressing the problems in the regulatory system by making it easier to undertake research in the UK will enhance the ability of health and social care services to deliver innovative research, which will ultimately benefit patients, the public and the world population in general.

The problem under consideration now

6. So that problems in research regulation could begin to be addressed quickly, the HRA was created as an interim SpHA on 1 December 2011. With the National Research Ethics Service (NRES) at its core, this is enabling the benefits of the new research regulator to be realised quickly. The HRA is beginning work to facilitate timely, high quality research through the creation of a unified approval process and by promoting consistent and proportionate standards for compliance and inspection. This will help to address the combined effect of individual legal and policy requirements for the approval of health research. The HRA is also providing an advice service and guidance and information for researchers to help make it easier for them to get research up and running. These initiatives will make it easier to undertake research in the UK reducing bureaucracy and encouraging organisations to fund research in the UK thereby contributing to the UK's economic growth. However as a SpHA, the HRA's functions are at the discretion of Ministers. Stakeholders have expressed concerns about the limited stability and independence that this provides; these are key to attract UK investment in research.
7. Independence is essential to the HRA's purpose of protecting and promoting the interests of participants, potential participants, and the public in research. Regulating research, protecting patients from unethical research whilst enabling them to benefit from participating in research, requires expertise in research and regulation and hence these are best provided as a stand-alone function at a national level. As a national body, HRA is best able to work with others with an interest in research to streamline regulation and make it proportionate to risk. At arm's-length from Government the HRA is able to act, and be seen to act independently ensuring political impartiality.
8. Establishing the HRA as a NDPB means that its functions will be clearly laid out in legislation that has been scrutinised by Parliament rather than simply set out in directions given by the Secretary of State. As a NDPB, the HRA will be held to account for delivery of objectives and its stewardship of public funds and will be expected to comply with requirements set out by the Department and Government (for example, *Managing Public Money*).
9. In addition, as a SpHA the HRA is generally limited to exercising Secretary of State's functions relating to the health service. Establishing it as a NDPB will provide a stronger basis for promoting a consistent system of regulating research across health and social care and across the UK which is currently being undertaken through agreements. Establishing the HRA as a NDPB will also mean that the HRA could be given functions relating to regulation of embryo research, subject to the outcome of consultation and parliamentary approval.
10. The Department of Health is committed to establishing a stable system architecture as part of the changes being made to the wider health system. It intends SpHAs to only be established for specific purposes and for time limited periods. Where functions are to be given to other bodies on a permanent basis, SpHAs are intended to be preparatory vehicles to support a smooth and safe transition of functions to the independent body which is to be established at arm's-length of Government. Although the provisions in the Health and Social Care Act 2012 do not apply to the HRA SpHA, we intend to be consistent with the spirit of this legislation.

Analytical narrative

11. The Department of Health's arm's-length bodies review *Liberating the NHS: Report of the arm's-length bodies review* sought to simplify the regulatory landscape. The review said that functions will only take place at a national level where it makes sense to do so ensuring that ALB's have clearly defined functions and that where functions are better delivered by other parts of the system, they are devolved to the right level. Based on the ALB's findings, the review recommended that ALBs only undertake functions where:
 - there is a scarcity of capability and expertise meaning the functions are best undertaken at a national level;

- the functions need to be performed independently of Ministers to ensure political impartiality; or
 - the functions provide accountability and assurance to patients, service users and the taxpayers by independently establishing the facts.
12. Protecting participants and potential participants from unethical research whilst enabling patients and the public to benefit from research, requires expertise in regulation and ethical issues. Research regulation provides participants, potential participants and the public with assurance that there are appropriate safeguards which they can be confident in. Political impartiality by being at arm's-length of Government will ensure that above all, the HRA acts, and is seen to act, in the interests of patients and the public whose interests it must protect and promote. People involved in ethically reviewing research want assurance that the role they undertake will not be influenced by politics and that their focus will remain on the ethics of the research. Concerns are being raised about the HRA as a SpHA being too close to the Department of Health.
13. In simplifying the regulatory landscape and creating a stable system architecture, the Government, through the Health and Social Care Act 2012, intends future SpHAs to act as preparatory vehicles for the smooth and safe transition of functions to arm's-length bodies where functions are given to ALBs. Establishing the HRA as a NDPB is therefore consistent with the policy set out in the Act.
14. The AMS review of regulation and governance in health research reported that a complex and bureaucratic regulatory environment had evolved over a number of years. The review received around 280 submissions in response to its call for evidence and its recommendations supported the creation of the HRA as an independent regulator for research.

Policy objectives and intended effects

15. The policy objective is to establish the HRA as part of a stable health and social care system, as an independent regulator of research with an overarching objective to protect and promote the interests of participants, potential participants and the public in research. As a stable part of the system, the HRA will continue to drive efficiency and value for money in facilitating research. The intended benefits are to:
- put the HRA at arm's length from Ministers on a stable and independent footing that has been assured by parliamentary scrutiny;
 - set out the HRA's functions clearly in legislation that has been approved by Parliament;
 - give the HRA a broader formal remit which provides a stronger basis for promoting a consistent system of regulation of research across health and social care and across the UK;
 - enable the HRA to regulate embryo research, subject to the outcome of public consultation and Parliamentary approval on this function;
 - strengthen public confidence in the protection that the regulatory framework provides for individuals, while improving the cost-effectiveness of the delivery of research in the UK;
 - provide for accountability to Parliament and the public for the delivery of functions to make research easier;
 - give the HRA the stability and independence that will enable it to put the interests of participants and potential participants in research and the public first and to be seen to be free from political interference; and
 - to provide assurance for funders of research that the HRA will continue to make research easier to get up and running in the UK through proportionate regulation that continues to be robust and expertise in ethical matters, encouraging long-term investment in research in the UK.

Underlying causes of the problem?

16. Establishing the HRA as a SpHA on 1 December 2011 is enabling prompt steps to be taken to improve the regulation of research. However in line with the arm's-length bodies review report, *Liberating the NHS: Report of the arm's-length bodies review*, the Department of Health's intention is for the HRA to be put at arm's-length of Government as it undertakes functions at a national level which require expertise in ethical matters and in regulating research. The ability to act, and be seen to act independently is vital to be able to protect and promote the interests of participants, potential participants and the public in research. Independence will ensure that participants, potential participants and the public's interests come first, and that the HRA is seen to be free from political interference and so participants, potential participants and the public can be confident in the protection that the regulatory framework provides.
17. The HRA will form part of an ALB sector that achieves better outcomes, is more responsive to patient's needs and has increased independence and clear accountability at every level, and ensures value for money. In seeking to create a stable health and social care system, establishing the HRA as a NDPB is vital so that the HRA is a permanent and clearly independent body which can only be abolished through primary legislation. As a SpHA, the HRA's role, remit or even existence can be changed by Government at any point. For industry, stability and independence provides assurance that, as a NDPB the HRA will continue the work to make it easier to undertake research in the UK, encouraging industry to invest in the UK on a long-term basis.
18. Considerable stakeholder engagement, and debate in Parliament has shown substantial and widespread support for the HRA's establishment but also concern that steps need to be taken quickly to give it greater stability and independence.

Policy options

19. Two options have been considered.
20. Option 0: retain the HRA as a SpHA. The Department of Health established the HRA as an interim SpHA to promote and protect the interests of patients and the public in health research with the intention of putting it on a stable and independent footing when parliamentary time allowed.
21. Option 1: establish the HRA as a Non Departmental Public Body (NDPB) to put the current body on a stable and independent footing enabling it to continue to protect and promote the interests of participants, potential participants and the public in research. This option is supported by the AMS.
22. Option 1 is the preferred option as it would put the HRA at arm's-length of Government enabling it to act independently in the interests of participants, potential participants and the public, and be seen to be free from political interference. As a NDPB, the HRA will have stability, which will assure the life sciences industry that it will continue to make it easier to undertake research in the UK through proportionate regulation that continues to be robust. It also allows the HRA to formally take on functions wider than the Secretary of State's health related functions that the SpHA is directed to undertake.

Impacts, costs and benefits of the preferred option

23. The intention is to create a research environment in which the interests of participants, potential participants and the public are protected and promoted in research. The preferred option, establishing the HRA as a NDPB will give the HRA stability and independence as part of a stable health and social care system. Through cooperation with other regulatory and advisory bodies and the devolved administrations, the HRA will be well placed to protect and promote the interests of participants, potential participants and the public in health research. As a NDPB, the HRA will continue the work being undertaken by the SpHA to make research easier to get up and running through robust and proportionate regulation, enabling more research benefiting patients and the

public by providing new knowledge to improve health outcomes. More research which identifies new ways of preventing, diagnosing and treating disease will increase the quality and productivity of the NHS and enable resources to be better used.

Costs

24. We have considered the costs the National Audit Office (NAO) identified in its report *Reorganising central government* which looked at the costs of re-organisations. As establishing the HRA as a NDPB does not in itself involve reorganisation, the costs of establishing the NDPB are expected to be low. Although efficiencies are expected from all arm's-length bodies, these are not as a direct result of establishing the NDPB and therefore are not included in this Impact Assessment.
25. Establishing the HRA as a NDPB will enable it to be given other functions, if appropriate and subject to the outcome of a public consultation on proposals relating to the research related functions of the Human Fertilisation and Embryology Authority and Human Tissue Authority. If any additional functions are given to the HRA, these will be the subject of a separate Impact Assessment.

Annual costs as a NDPB

26. It is expected that staff will transfer from the SpHA HRA to the NDPB on their current terms and conditions. No significant redundancies are foreseen as a direct result of establishing the HRA as a NDPB and additional staff requirements are not anticipated over and above the staff costs of the SpHA. Following consultation, if the Government decided to transfer the research related functions of the Human Fertilisation and Embryology Authority to HRA, these would be the subject of a separate Impact Assessment.
27. As a NDPB, the HRA board will consist of up to 4 non executive directors in addition to a Chair and Chief Executive. The Department of Health is seeking to recruit 2 non-executive directors to the board of the SpHA. On establishing the NDPB, we expect to appoint 1 or 2 additional non-executive directors resulting in recurrent additional costs of £14,000 per annum.

Transition costs on establishment of the NDPB

28. In terms of transitional costs to recruit the 1 or 2 additional non-executive directors to the HRA board on establishment as a NDPB, these are estimated at £10,000 based on newspaper and online advertising.
29. IT related costs are often one of the main costs to reorganisations but whilst the SpHA may incur IT related costs over the next period in fulfilling its functions for example in developing a unified approvals process, no additional IT related costs have been identified as part of establishing the NDPB.
30. The SpHA is already rationalising its estates in line with Government policy and no new leases or acquisitions are foreseen on establishing the HRA as a NDPB therefore no transitional costs are foreseen. Any future decision on locations of its offices when the HRA becomes a NDPB will be a matter for its board but will need to take into account Government policy on estates.
31. As a SpHA with clear sight on being establishing as a NDPB subject to the passage of legislation, the HRA SpHA will be able to plan for the transition so it is envisaged that there will not be significant one off branding or communication costs.
32. A programme of work is already underway with the SpHA to move towards shared services arrangements where possible in areas such as HR and finance. This should all be in place by the time the HRA is established as a NDPB and additional costs are not expected. As a SpHA, the HRA will incur audit costs and costs of consultation and it is not envisaged that NDPB will incur costs over and above those the SpHA will incur.

33. No significant indirect project and planning costs associated with the transition from a SpHA to a NDPB have been identified. Whilst some staff may be involved in transition planning, this is likely to be absorbed as part of business as usual.

Annual profile of costs (£'000) constant prices

Transition Costs	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9
IT	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Estate	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Branding and Communication	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Corporate functions	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Indirect costs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Staff recruitment	10	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL	10	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Additional Annual Costs										
Staff	14	14	14	14	14	14	14	14	14	14
TOTAL	24	14	14	14	14	14	14	14	14	14

Benefits

34. Most of the benefits will be qualitative benefits which are difficult to monetise. As a more stable and independent body with enhanced credibility, the HRA will be better placed to protect and promote the interests of participants, potential participants and the public in research. The benefits of establishing the HRA as a NDPB are that:
- the HRA will be at arm's-length of Ministers on a stable and independent footing that has been assured by parliamentary scrutiny;
 - the HRA's independent status will provide the public with assurance that the systems in place to regulate health and social care research put the interests of participants, potential participants and the public first and that the HRA is seen to be free from political interference;
 - for funders of research including the life sciences industry and charities, the stability of establishing the HRA as a NDPB will provide assurance that the HRA will continue to make it easier to undertake research in the UK through robust and proportionate regulation, encouraging long-term investment in research in the UK;
 - the HRA's functions will be clearly set out in legislation that has been approved by Parliament;
 - as a NDPB the HRA will be accountable to Parliament and the public for the delivery of its functions to make research easier;
 - the HRA will be given a broader legal remit which will provide a stronger basis for promoting a consistent system of regulation of research across health and social care and across the UK. As a NDPB, the HRA will be able to regulate embryo research, subject to the outcome of the consultation and parliamentary approval; and
 - It will strengthen public confidence in the protection that the regulatory framework provides for individuals, enabling greater trust in the HRA and confidence in health research so it can improve the cost effectiveness of research undertaken in the UK.

Equality Analysis

35. The Department will be publishing a separate Equality Analysis alongside the Impact Assessment.

One in one out

36. The Department has considered non legislative approaches to streamlining the regulation of research but ultimately primary legislation is required to establish the HRA as a permanent, stable and independent body responsible for ensuring research is ethical.

37. As a permanent part of the regulatory system, the HRA will protect and promote the interests of participants, potential participants and the public in research whilst at the same time reduce the burdens of the current regulatory framework by continuing to streamline and simplify approval processes.

Key risks and assumptions

38. The Department envisages that the transition from SpHA to NDPB status will be relatively seamless. The Department therefore envisages that there will be no significant reorganisation as the functions that the HRA undertakes will remain the same. Nevertheless we have considered each of the costs that the NAO identified associated with reorganisations to ensure that potential costs have been properly considered.
39. Where some costs are anticipated, in the absence of detailed information, the Department has relied on assumptions based on previous cost estimates. Whilst the costs are based on the assumption that there will not be any reorganisation and therefore expected cost estimates are low, there is a risk that the costs may be underestimated. However, given the size of the organisation, any variation from estimate is likely to be small.
40. NDPBs are not automatically exempt from VAT. It is our intention to seek exemption from VAT. There is a risk that if exemption is not granted then this could distort procurement decisions with implications for the costs of the organisation.
41. As the benefits are qualitative, it has not been possible to monetise these and this Impact Assessment assumes that the benefits that stability and independence will provide will outweigh the low level of costs that have been identified.