

Review of the regulation and governance of medical research



Call for evidence on the function and scope of a proposed 'single research regulator'.

Earlier this year, the Academy of Medical Sciences was commissioned by Government to undertake an independent review of the regulation and governance of UK medical research. A first call for evidence inviting views on issues relevant across the regulation and governance framework closed in June 2010. Following the publication of the Department of Health's report on arm's-length bodies¹ (ALB report) in July, the Academy has taken the decision to issue this **second call for evidence** to provide all interested parties with an opportunity to consider the proposals in the ALB report with direct relevance to the regulation of medical research.

This call for evidence focuses on the Government's wish to consider:

- The merits of placing responsibility for different aspects of medical research regulation within a 'single research regulator'.
- The future of the National Research Ethics Service and reorganisation of the research regulatory activities of the Human Tissue Authority and the Human Fertilisation and Embryology Authority.

To ensure that all submissions can be considered within the timeframe in which the Academy has been invited to report:

- Respondents are invited to provide written evidence by 5pm on **Tuesday 31 August**. Submissions by this date will inform the next discussion of the Academy working group undertaking this review.
- Respondents unable to meet this deadline are asked to notify the Academy by 31 August of their intention to submit evidence and to highlight substantive issues that will form the basis of their submission. The final deadline for submissions is 5pm on **Tuesday 14 September**.

Why is the review taking place?

In March 2010, then Health Secretary Andy Burnham announced a Government commission for the Academy of Medical Sciences to conduct an independent review of the regulation and governance of UK medical research. The Academy had highlighted the need for this review in 'Reaping the rewards: a vision for UK medical science', published in January 2010.²

¹ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117691

² Academy of Medical Sciences (2010). *Reaping the rewards: a vision for UK medical science*. <http://www.acmedsci.ac.uk/index.php?pid=99&puid=172>

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Following the election, the new Government reiterated the role of the Academy review as part of their wider drive to cut the bureaucracy involved in the regulation of medical research. Support for the study was given by the Rt Hon David Willetts MP, Minister for Universities and Science at a press briefing in May 2010.³ The Health White Paper stated the Government's commitment, 'to consider the legislation affecting medical research, and the bureaucracy that flows from it, and bring forward plans for radical simplification' in light of the Academy review.⁴

What are the aims and scope of the review?

The terms of reference for the Academy review are provided in Box 1. The review will concentrate on research involving human participants, their tissues or data and will not deal in detail with the regulation and governance surrounding the use of animals in research. In addition to the focus on all stages of **clinical trials**, the review will also consider **experimental medicine**⁵ and **epidemiological studies** (i.e. studies that require access to patient data). Please see Annex I for a list of some of the legislation, conventions and regulatory bodies that are within the scope of the review.

Box 1: Terms of reference

The Academy's review of the regulation and governance of medical research will:

- Review the regulatory and governance environment for medical research in the UK, with a particular focus on clinical trials.
- Identify key problems and their causes, including unnecessary process steps, delays, barriers, costs, complexity, reporting requirements and data collection.
- Make recommendations with respect to the regulatory and governance framework that will: increase the speed of decision-making; reduce complexity; and eliminate unnecessary bureaucracy and costs.

In making recommendations for change, the need to ensure the protection of the safety of participants, as well as the need for appropriate arrangements for governance and accountability, will be central.

³ <http://www.acmedsci.ac.uk/p118pressid67.html>

⁴ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117353

⁵ The term *experimental medicine* is used to describe 'investigations in humans to identify the cause of disease and test the validity and importance of new discoveries and treatments'.
<http://www.ukcrcepm.org.uk/aboutus/Pages/faqs.aspx>

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Current status of the review

The Academy's review is being undertaken by a working group chaired by Sir Michael Rawlins FMedSci and we aim to publish the final report, containing the conclusions and recommendations of the review by the end of the year, subject to approval by the Academy's Council. For further information on the review please visit: <http://www.acmedsci.ac.uk/p47prid80.html>.

A first call for evidence on the regulation and governance of medical research closed on 1 June 2010. The Academy is now issuing a **second call for evidence**, focusing on the Government's proposals for a 'single research regulator.'

Department of Health report on arm's-length bodies

The Department of Health published their 'Report on the arm's-length bodies review' on 26 July.⁶ The report sets out steps to abolish and reorganise arm's-length bodies in an attempt to: 'create a more streamlined sector'; ensure 'less bureaucracy'; 'reduce intervention'; and enable 'greater efficiency through contestability'. Information on the planned changes is provided in the report and it is recommended that respondents familiarise themselves with these before replying to this call for evidence.

A new research regulator

Paragraphs 3.21 and 3.22 of the ALB report set out specific proposals for placing the responsibilities for different aspects of medical research regulation within one arm's-length body and refer to the Academy's ongoing review:

(Extracts from the ALB report).

3.21 We have asked the Academy of Medical Sciences to conduct an independent review of the regulation and governance of medical research which is expected to report in autumn 2010. Currently a number of different arm's-length bodies have responsibility for different aspects of research regulation, including giving permissions. There is a strong argument for rationalising this and creating greater strategic coherence around research by placing responsibility for these different aspects of medical research regulation within one arm's-length body that would perform a stand-alone technical function as a research regulator. This would streamline the process of gaining permission to undertake medical research, making it more attractive to universities and health institutions. Moreover, there is potential for a single research regulator to have wider cross-government reach.

3.22 In the light of the Academy of Medical Sciences review, we will consider legislation affecting medical research, and the bureaucracy that flows from it, and bring forward plans for radical simplification.

⁶ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117691

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National Research Ethics Service (NRES), Human Tissue Authority (HTA) and the Human Fertilisation and Embryology Authority (HFEA).

The ALB report also proposes that:

- *'...the future of the National Research Ethics Service is considered as part of the wider Academy of Medical Science's review of research regulation with a view to moving this function into a single research regulatory body'* (paragraph 3.63) and;
- The research regulatory activities of the Human Tissue Authority and Human Fertilisation and Embryology Authority are within the scope of the Academy of Medical Sciences review and, *'subject to the outcome of that review, there could be significant advantage in consolidating these functions'* into a single research regulatory body (see paragraphs 3.26 & 3.27).

In addition to the paragraphs cited above, further information is provided in the ALB report on the Government's principles for the arm's-length body sector and specific proposals in relation to the HTA and HFEA.

Suggested evidence for submission:

Following the Department of Health's ALB report, the Academy is now issuing a **second call for evidence**, focusing on proposals for a 'single research regulator'. Evidence can be provided on any issues relating to the Government's proposal of a 'single research regulator'; the future of the National Research Ethics Service (NRES); and research regulatory activities of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA).

The ALB report considers only a limited number of the bodies involved in the regulation and governance of medical research. The Government has yet to announce its conclusions about the future of Advisory Non-Departmental Public Bodies (ANDPBs). Some ANDPBs organisations are relevant to the regulation of medical research and personal data and are considered within the scope of the Academy review. Respondents are encouraged to consider the possible scope and function of a 'single research regulator' in the context of the wider regulatory and governance framework under review by the Academy (see Annex I and II). We ask that respondents include, wherever possible, robust quantitative and qualitative evidence (e.g. case studies) to support their submissions. In light of the Government's proposal for a 'single research regulator', evidence might address the following questions:

- What are the possible **advantages and challenges** of 'placing the responsibilities for different aspects of medical research regulation within one arm's-length body'?
- In light of the stated aims in the ALB report, what should be the future of the **National Research Ethics Service** and the research regulatory activities of the **Human Fertilisation & Embryology Authority** and **Human Tissue Authority**?

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- Research involving human participants, their tissues or data currently involves multiple approvals and regulatory bodies (e.g. granting ethical approval, access to tissue or patient data, and local NHS R&D approval). A schematic representation of some of the approvals involved is provided in Annex II. **Which approvals or 'permissions' should be within the remit of a 'single research regulator' to maximise its effectiveness and impact?**
- In addition to granting permissions for research, a range of other functions and powers are currently distributed across several bodies. These related roles include monitoring research projects, inspecting research sites and facilities, public engagement, exploring and preparing for novel ethical issues raised by research, and an 'educational' role in improving the regulatory process and professional standards of research practice. **What should be the key functions of a 'single research regulator'?**
- **How would a 'single research regulator' best fit into the wider regulatory and governance framework?** The broad regulatory environment includes, for example, authorities that have a legal duty to approve specific subsets of research, organisations which look to promote best practice in information and research governance, and other bodies that grant permission for research to be undertaken on NHS patients. **How might a 'single research regulator' interface with other bodies or approvals to create an efficient and effective environment for public and private sector research?**
- The ALB report states there is potential for a single research regulator to have 'wider cross-government reach'. **Should the scope of the 'single research regulator' encompass health-related research permissions currently outside the remit of the Department of Health (e.g. Ministry of Defence, Ministry of Justice) or other areas of research affecting health outcomes and public health?**
- **What would be the optimal operational and governance arrangements for a 'single research regulator'?**
- **Should a new 'single research regulator' have a UK-wide remit and how would this fit with current structures in the devolved nations?**
- In isolation, the creation of a 'single research regulator' will not deliver an effective regulation and governance system that facilitates advances in medical research and ensures the safety of research participants and the public; **what other significant measures are needed to improve the regulation and governance framework for medical research?** If relevant, respondents may want to cross-refer to an earlier submission to the AMS review.

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How and when to submit evidence:

The Academy has taken the decision to issue a **second call for evidence** to provide all interested parties with an opportunity to consider the proposals in the ALB report. To ensure that responses can be considered within the timeframe in which the Academy has been invited to comment, it has been necessary to stipulate a short deadline for this Call. We acknowledge the challenge this poses for respondents and to provide as much time as possible, we have included two phases to this call:

- Respondents are invited to provide written evidence by 5pm on **Tuesday 31 August**. Submissions by this date will inform the next discussion of the Academy working group undertaking this review.
- Respondents unable to meet this deadline are asked to notify the Academy by 31 August of their intention to submit evidence and to highlight substantive issues that will form the basis of their submission. The final deadline for submissions is 5pm on **Tuesday 14 September**.

Please submit evidence electronically, marked 'R&G review-single research regulator', to regulatoryreview@acmedsci.ac.uk. To notify the Academy of your intention to submit or if you wish to discuss your submission, please contact Dr Robert Frost (robert.frost@acmedsci.ac.uk; +44(0)2079695284) by Tuesday 31 August. If you do not wish to submit evidence but would like to be kept informed about the progress of the review please provide your contact details to the same address, marked 'R&G review-Contact'.

Confidentiality

A list of contributors and submitted evidence may be included on the Academy's website. Excerpts may also be included in publications arising from the review. Please notify us at the time of submission if you do not wish your name or evidence to be published. If you are submitting evidence on behalf of an organisation please provide the details of a named contact.

The Academy of Medical Sciences

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our Fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and public service. The Academy seeks to play a pivotal role in determining the future of medical science in the UK, and the benefits that society will enjoy in years to come. We champion the UK's strengths in medical science, promote careers and capacity building, encourage the implementation of new ideas and solutions – often through novel partnerships – and help to remove barriers to progress.

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Further information on the review is available at <http://www.acmedsci.ac.uk/> or by contacting:

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We are grateful to the Department of Health for providing a financial contribution towards this review, which is being carried out independently of Government. We are also very appreciative of the assistance provided by the Wellcome Trust and Cancer Research UK through the secondment of part-time staff to support this review.

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Annex I: Examples of the legislation, conventions and regulatory bodies that affect medical research

We recognise that the legislation in Scotland, Wales and Northern Ireland may differ. The review will cover the regulation and governance framework across the UK.

Current legislation and conventions include:

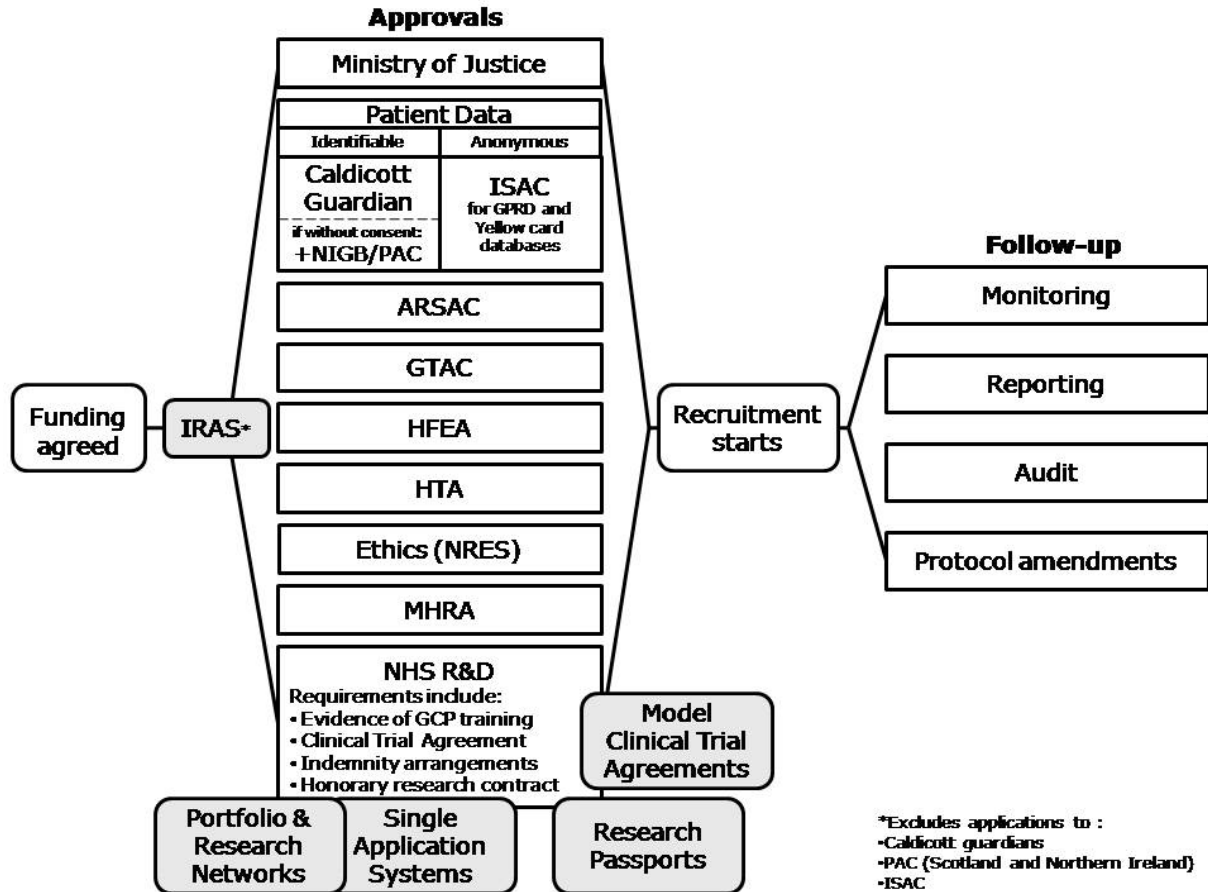
- Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data
- Data Protection Act 1998
- European Clinical Trials Directive and the regulations transposing the Directive into domestic law
- European Convention on Human Rights
- European Data Protection Directive
- Health and Social Care Act 2008
- Health Service (Control of Patient Information) Regulations 2002
- Human Tissue Act 2004
- Human Fertilisation and Embryology Act 2008
- Ionising Radiation (Medical Exposure) Regulations 2000, as amended 2006
- Medical Devices Regulations 2002
- Mental Capacity Act 2005
- NHS Act 2006
- Research Governance Framework for Health and Social Care 2nd edition, 2005

Bodies involved in regulation, governance and advice include:

- Care Quality Commission
- European Medicines Evaluation Agency
- Human Fertilisation and Embryology Authority
- Human Tissue Authority
- Information Commissioner's Office
- Medicines and Healthcare products Regulatory Agency
- National Information Governance Board
- NHS research ethics committees

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Annex II: Schematic of current regulatory and governance pathway



ARSAC	Administration of Radioactive Substances Advisory Committee
GTAC	Gene Therapy Advisory Committee
HFEA	Human Fertilisation and Embryology Authority
HTA	Human Tissue Authority
IRAS	Integrated Research Application System
ISAC	Independent Scientific Advisory Committee for MHRA database
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	NHS Trust or Local Health Board R&D office
NIGB	Health and Social Care National Information Governance Board
NRES	National Research Ethics Service
PAC	Privacy Advisory Committee