



## Review of the regulation and governance of medical research

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There is widespread and increasing concern that the process of medical research is being jeopardised by a regulatory and governance framework that has become unnecessarily complex and burdensome. The Academy of Medical Sciences has been commissioned by the Government to undertake an independent review of these issues to inform future government policy within and beyond the UK. Submission of evidence from all interested parties is invited. The call for evidence will close at 5pm on **Tuesday 1 June 2010**.

### **Why is the review taking place?**

In our report '*Reaping the rewards: a vision for UK medical sciences*', published earlier this year,<sup>1</sup> the Academy highlighted concerns that the regulatory framework for medical research had become over-burdensome and that streamlining and improving current regulation could represent a cost-effective approach to creating a more fertile and productive research environment. The report recommended that the UK should lead the world in creating a proportionate, risk-based regulatory framework for medical research involving humans that is fit for purpose and informed by an independent review of existing regulations. On Thursday 25 March, the Health Secretary Andy Burnham MP announced that the Government had commissioned the Academy to conduct an independent review of the regulation and governance of medical research, with a focus on clinical trials.<sup>2</sup>

### **What are the aims and scope of the review?**

We 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 cost.

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.

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<sup>1</sup> 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>

<sup>2</sup> <http://www.acmedsci.ac.uk/index.php?pid=118&pressid=63>

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The review will identify the current legislation, conventions and guidance that govern, regulate and influence the process of medical research, and the impact that these have individually and collectively. In addition to considering what is actually required by the regulatory framework, the review will also consider how it is interpreted in practice - and examine the reasons for any discrepancies between the two. 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**<sup>3</sup> and **epidemiological studies** (i.e. studies that require access to patient data). Please see the annex for a list of some of the legislation, conventions and regulatory bodies that are within the scope of the review.

### **How will the review be carried out?**

The Academy's review will be undertaken by a working group chaired by Sir Michael Rawlins FMedSci. The members of the working group will be announced shortly on the Academy's website.<sup>4</sup> The review will be informed by written and oral evidence. 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. We are grateful to the Department of Health for providing a financial contribution towards this review, which will be carried out independently of Government.

### **Who should respond to this call for evidence?**

This call seeks input from all organisations and individuals with an involvement or interest in the regulatory and governance framework around medical research. This may include: medical research scientists from all sectors including industry; medical research charities; research funders and regulators; patients and their representatives; and the general public. We would be very grateful if you would circulate this call for evidence to other interested parties.

### **Suggested evidence for submission:**

Evidence can be provided on any issues relating to the aims and scope of the review. We ask that respondents include, wherever possible, robust quantitative and qualitative evidence (e.g. case studies) to support their submissions. Evidence might address the following questions for the areas of medical research that we are considering (please see above for the scope of the review):

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<sup>3</sup> 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.ukcrcepmmed.org.uk/aboutus/Pages/faqs.aspx>

<sup>4</sup> <http://www.acmedsci.ac.uk>

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- What are the principles that should underpin the regulation and governance of medical research?
- What are the most significant regulatory and governance impediments to medical research in the UK? In each case, is the impediment caused by: the underpinning regulation (or absence of regulation); its implementation at national or local level; the guidance and support provided for researchers (or lack of it)?
- Which parts of the regulatory and governance framework are working well and why?
- What initiatives to reduce the burden of the regulatory and governance framework are currently in progress, both here and abroad?
- What can we learn from the regulatory and governance framework in the different nations of the UK and from outside the UK?
- What changes to the regulatory and governance framework would provide the greatest improvement to the progress of medical research, without putting patients at unnecessary risk?
- How might the medical research process evolve in the future? Does this raise any additional issues for the regulatory and governance framework?
- Is there a need for a more risk-based approach to medical regulation and how might this be developed and adopted?

### **How and when to submit evidence:**

Please submit evidence, preferably electronically, marked 'R&G review-Evidence', to [regulatoryreview@acmedsci.ac.uk](mailto:regulatoryreview@acmedsci.ac.uk). The call for written evidence will close at 5pm on **Tuesday 1 June 2010**. If you cannot submit within this timeframe or wish to discuss your submission please contact Dr Robert Frost by email ([robert.frost@acmedsci.ac.uk](mailto:robert.frost@acmedsci.ac.uk)) or telephone (+44(0)2079695284). 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

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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.

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

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## **Annex: 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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