EXPLANATORY MEMORANDUM TO

THE HEALTH RESEARCH AUTHORITY (ESTABLISHMENT AND CONSTITUTION) AMENDMENT ORDER 2012

2012 No. 1109

AND

THE HEALTH RESEARCH AUTHORITY (AMENDMENT) REGULATIONS 2012

2012 No. 1108

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instruments

2.1 The purpose of these instruments is to reconstitute the board of the Health Research Authority ("the Authority") so that the Authority will have greater independence and credibility to perform its functions for the purpose of protecting and promoting the interests of patients and the public in health research.

2.2 The Order changes the constitution of the Authority to provide that the Authority is to consist of non-officer members (including a chair) as well as officer members; and amends the functions of the Authority to express its purpose of protecting and promoting the interests of patients and the public in health research in light of the Authority's reconstitution with leadership and governance involving an independent chair and non-executive directors.

2.2 The Regulations provide for the appointment and term of office of the members of the Authority; for disqualification for appointment as a non-officer member of the Authority; for the termination of appointment; for the suspension of appointment; and powers relating to the appointment of a vice-chair of the Authority. Provision is also made to require the presentation by the Authority of an annual report at a public meeting; and changes are made to the provisions about the conduct of proceedings and meetings of the Authority.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The Order amends the Health Research Authority (Establishment and Constitution) Order 2011 ("the 2011 Order"). It changes the constitution of the Authority to provide that the Authority is to consist of a chair, non-officer members and officer members (whereas the 2011 Order constituted the Authority with two officers of the Authority). It amends the functions of the Authority to express the Authority's purpose of protecting and promoting the interests of patients and the public in health research in view of the Authority's reconstitution with a board which includes non-officers (whereas the 2011 Order provided for functions with an operational focus in view of the *ex officio* board constituted by the 2011 Order).

4.2 The Regulations amend the Health Research Authority Regulations 2011 ("the 2011 Regulations"), which made provision about the membership and procedure of the Authority, a Special Health Authority established under section 28 of the National Health Service Act 2006 by the 2011 Order. They provide for the appointment of a chair and non-officer members (whereas the 2011 Regulations provided only for the appointment of a chief executive and one other executive member of the Authority) and for disqualification or suspension of members. They make ancillary changes to meetings and other proceedings of the Authority.

5. Territorial Extent and Application

5.1 These instruments apply to England.

6. European Convention on Human Rights

As the instruments are subject to negative resolution procedure and do not amend primary legislation, no statement is required.

7. Policy background

7.1 As explained in the Explanatory Memorandum to the 2011 Order and Regulations, those instruments established the Health Research Authority as a Special Health Authority, as the first step in fulfilling the Government's commitment, following an independent review of health research regulation and governance, to create a new body, i.e. ultimately a non-Departmental public body, to combine and streamline the approvals for health research.

7.2 The Health Research Authority was established with substantive functions, including the research ethics committee service as the Health Research Authority's core. Details of the Health Research Authority's functions were set out in the Health Research Authority Directions 2011 (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/Public

ationsLegislation/DH_131576). In addition to activities related to the research ethics committee service, these Directions covered in particular the creation of a unified approval process for health research and the promotion of consistent, proportionate standards for compliance and inspection. The Health Research Authority was initially constituted with an interim executive-only board in view of the fact that it would be possible to make interim *ex officio* appointments from among the existing officers of the Health Research Authority.

7.3 It was intended that the 2011 Order and Regulations would be amended this year to provide for the Health Research Authority to have a chair and non-officer members as well, so that it would have greater independence and credibility to perform its functions for the purpose of protecting and promoting the interests of patients and the public in health research. From that point, the Health Research Authority could also have conferred on it certain additional functions which call for it to have leadership and governance involving an independent chair and non-executive directors if it is to command patients' and public confidence in its performance of those functions. Such functions include in particular the Secretary of State's function in regulation 5(a) of the Health Service (Control of Patient Information) Regulations 2002 of approving the processing of confidential patient information for medical research, planned for conferral by Directions by April 2013.

7.4 In accordance with this intention, the current instruments therefore reconstitute the Health Research Authority and amend its functions to express the Health Research Authority's purpose.

7.5 It is intended to publish clauses to establish the Health Research Authority as a non-Departmental public body for pre-legislative scrutiny in the second session of this Parliament.

8. Consultation outcome

8.1 The current instruments have not been the subject of separate consultation. They are the second of three steps in the establishment of the Health Research Authority (the first step being its initial establishment as a Special Health Authority with an executive-only board and the third step being its intended establishment as a non-Departmental public body), following the recommendation of an independent review by the Academy of Medical Sciences of the regulation and governance of health research.

8.2 Some 280 written submissions were received in response to the Academy's calls for evidence. The Academy reported in January 2011 and recommended that existing bodies' functions relating to health research approvals should be brought together in a new body as soon as possible.

8.3 The Government announced in March 2011 that it would therefore establish such a body in 2011, initially as a Special Health Authority.

9. Guidance

9.1 The Department of Health will provide publicity about the appointments to, and the purpose and functions of, the Health Research Authority on the Department of Health web site.

10. Impact

10.1 The purpose of the Health Research Authority as a Special Health Authority is to protect and promote the interests of patients and the public in health research. It will protect patients from unethical research while enabling them to benefit from participating in research by simplifying processes for ethical research. The Health Research Authority's role in combining and streamlining the health research approvals and incidental functions previously undertaken by many organisations is intended to reduce the regulatory burden on researchers. This will improve the timeliness of decisions about research projects and hence the cost-effectiveness of their delivery in the UK, increasing opportunities for patients here to benefit.

10.2 No negative impact on business, charities or voluntary bodies is foreseen.

10.3 No negative impact on the public sector is foreseen.

10.4 An Impact Assessment has not been prepared for these instruments.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The Health Research Authority's performance of its functions will be reviewed by the Department of Health in accordance with the standard framework agreement which the Department of Health is introducing for all its arm's-length bodies.

13. Contact

Bill Davidson at the Department of Health (tel: 0113 254 6184 or email: bill.davidson@dh.gsi.gov.uk) can answer any queries regarding the instruments.