NATIONAL HEALTH SERVICE, ENGLAND

The Health Research Authority Directions 2011

The Secretary of State gives the following Directions in exercise of the powers conferred by sections 7, 8, 71(4), 272(7) and (8) of the National Health Service Act 2006(**a**).

Citation, commencement, application and interpretation

1. (1) These Directions may be cited as the Health Research Authority Directions 2011 and they shall come into force on 1st December 2011.

(2) These Directions are given to the Health Research Authority(**b**).

(3) In these Directions—

"Appointing Authority" means a person or body which establishes Research Ethics Committees, recognises Research Ethics Committees, and appoints members of such Committees;

"Authority" means the Health Research Authority established by the Health Research Authority (Establishment and Constitution) Order 2011;

"health research" means any research for the purposes covered by paragraph 13 of Schedule 1 of the National Health Service Act 2006**,** including any research for which other legislation requires review by a Research Ethics Committee recognised by or on behalf of the Secretary of State;

"Research Ethics Committee" means a group of people appointed to assess whether research proposals relating to the health service conform to recognised ethical standards.

Functions of the Authority relating to facilitation and promotion of health research

2. The Secretary of State, with a view to the Authority facilitating and promoting health research, directs the Authority to exercise the following functions, having regard to the objective of protecting and promoting the interests of patients and the public—

(a) to facilitate—

(i) health research which conforms to applicable standards and statutory requirements; and

(ii) where health research does not conform to those applicable standards or statutory requirements, intervention by bodies with relevant intervention powers to ensure conformity;

(b) to co-operate for the purposes of creating a unified approval process for health research with persons or bodies (including by entering into agreements or memoranda of understanding), including the Administration of Radioactive Substances Advisory Committee(**c**) and its secretariat at the Health Protection Agency(**d**), the Human Fertilisation and Embryology Authority(**e**), the Medicines and Healthcare Products Regulatory Agency(**f**) and the Secretary of State;

(**a**) 2006 c. 41; by virtue of section 271 of the Act, the functions of the Secretary of State under those sections as exercised in making these Directions are exercisable only in relation to England.

(**b**) The Health Research Authority is established by the Health Research Authority (Establishment and Constitution) Order 2011, S.I. 2011/2323.

(**c**) Established by regulation 3 of the Medicines (Administration of Radioactive Substances) Regulations 1978, S.I. 1978/1006, as amended by S.I. 2005/2754 and S.I. 2006/2407.

(**d**) Established by section 1 of the Health Protection Agency Act 2004 c. 17.

(**e**) Established by section 5 of the Human Fertilisation and Embryology Act 1990 c. 37.

(**f**) Established as an executive agency of the Department of Health.

(c) to co-operate for the purposes of promoting consistent, proportionate standards for compliance and inspection with persons or bodies (including by entering into agreements or memoranda of understanding), including the Administration of Radioactive Substances Advisory Committee and its secretariat at the Health Protection Agency, the Care Quality Commission(**a**), the Chief Medical Officer, the Health and Social Care Information Centre(**b**), the Human Fertilisation and Embryology Authority, the Human Tissue Authority(**c**), the Medicines and Healthcare Products Regulatory Agency, the National Information Governance Board(**d**) and the Secretary of State;

(d) to co-operate to share information, which it receives in the course of carrying out its functions, with such persons or bodies as it considers appropriate, in accordance with its functions and the Data Protection Act 1998(**e**), to avoid duplication of effort by providers and recipients of information relevant to the Authority's functions;

(e) to collaborate with, to the extent that the Authority considers necessary, the Secretary of State for Health, the Scottish Ministers, the Welsh Ministers and the Department for Health, Social Services and Public Safety for Northern Ireland, in the exercise of its functions;

(f) to co-operate with other Appointing Authorities, where appropriate, to establish sufficient provision for Research Ethics Committee review and to facilitate the submission of applications to an appropriate and convenient Research Ethics Committee;

(g) to consult with persons or bodies as it considers appropriate, such as those referred to in sub-paragraphs (b), (c) and (e), prior to publishing guidance on matters relevant to health research.

Functions of the Authority relating to the establishment of Research Ethics Committees

3. The Secretary of State, with a view to establishing Research Ethics Committees, directs the Authority to exercise the following functions—

(a) to establish, as necessary and expedient in view of demand for the review of the ethics of health research, Research Ethics Committees—

(i) to act for the whole or part of a geographical area;

(ii) to act in relation to particular descriptions or classes of health research; or

(iii) to act for a combination of both sub-paragraphs (i) and (ii);

(b) to recognise, as necessary and expedient in view of demand for the review of the ethics of health research including where the law requires it, Research Ethics Committees—

(i) to act for the whole or part of a geographical area;

(ii) to act in relation to particular descriptions or classes of health research; or

(iii) to act for a combination of both sub-paragraphs (i) and (ii);

(c) to impose conditions or limitations on the establishment or recognition of Research Ethics Committees under sub-paragraphs (a) and (b);

(d) to revoke a recognition or vary or revoke any conditions or limitations imposed under sub-paragraphs (a), (b) and (c), abolish a Research Ethics Committee it has established, merge it with another Research Ethics Committee, or nominate a Research Ethics Committee to act on behalf of another Research Ethics Committee, if it ceases to operate;

(e) to make arrangements to provide Research Ethics Committees with such accommodation and facilities as the Authority considers necessary to enable them to perform their

(**a**) Established by section 1 of the Health and Social Care Act 2008 c. 14.
(**b**) Established by article 2 of the Health and Social Care Information Centre (Establishment and Constitution) Order 2005, S.I. 2005/499.
(**c**) Established by section 13 of the Human Tissue Act 2004 c. 30.
(**d**) Established by section 250A of the National Health Service Act 2006 c. 41. (Section 250A was inserted by section 157 of the Health and Social Care Act 2008 c. 14).
(**e**) 1998 c. 29.

functions (including arrangements for such administration, maintenance, cleaning and other services as it considers necessary);

(f) to make arrangements for the appointment of such administrative and other staff as the Authority considers necessary to enable Research Ethics Committees to perform their functions, and for the Authority to perform its functions in respect of Research Ethics Committees;

(g) to appoint members of Research Ethics Committees;

(h) to appoint officers of Research Ethics Committees, extend their tenure of appointment and terminate their appointment, in accordance with the terms of their appointment;

(i) to indemnify members of Research Ethics Committees for which it is the Appointing Authority against liabilities to third parties for loss, damage or injury arising from the carrying out by the members of Research Ethics Committee functions;

(j) to participate in the National Health Service Litigation Authority's Liabilities to Third Parties Scheme (**a**);

(k) to develop and manage a national training programme for members and officers of Research Ethics Committees;

(l) to develop, implement and maintain standard operating procedures for Research Ethics Committees and consistent practice by Research Ethics Committees;

(m) to develop and operate a quality assurance programme to encourage a consistently high level of service from Research Ethics Committees to their applicants, including accreditation of Research Ethics Committees based on regular audit of their operation, and an appraisal scheme to support committee officers in performing their duties;

(n) to monitor the extent to which Research Ethics Committees adequately perform their functions, through their annual reports, their accreditation status and other mechanisms for quality assurance provided by the Authority;

(o) to provide any other assistance, advice and support to Research Ethics Committees on procedural matters as may be necessary to ensure consistency between Research Ethics Committees;

(p) to establish and publish an appeals process against decisions of Research Ethics Committees;

(q) to handle appeals against decisions of Research Ethics Committees in accordance with the published appeals process referred to in sub-paragraph (p);

(r) to fund Research Ethics Committees with a sum in respect of each financial year equal to the amount of expenditure which it considers may be reasonably incurred by the Research Ethics Committees in that year for the purpose of performing their functions;

(s) to pay members of Research Ethics Committees such expenses and other allowances as it may determine; and

(t) to establish and manage regional centres where appropriate to support the functions of Research Ethics Committees or of the Authority in respect of Research Ethics Committees.

Signed by authority of the Secretary of State for Health

Simone Bayes
Member of the Senior Civil Service
Department of Health

1 December 2011

(**a**) *See* regulation 3 of the National Health Service (Liabilities to Third Parties Scheme) Regulations 1999, S.I. 1999/873 which provides for a Special Health Authority to be eligible to participate in the National Health Service Litigation Authority's Liabilities to Third Parties Scheme.