NATIONAL HEALTH SERVICE, ENGLAND

The Health Research Authority Directions 2013

The Secretary of State gives the following Directions in exercise of the powers conferred by sections 7(1), 8, 71(4), 272(7) and (8) and 273(1) 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 2013 and come into force on 1st April 2013.

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

(3) In these Directions—

"the Act" means the National Health Service Act 2006;

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

"relevant health research" means any research for the purposes covered by paragraph 13 of Schedule 1 to the Act(c), 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 committee established to advise on the ethics of research in human beings and recognised for that purpose by or on behalf of the Secretary of State in exercise of the powers in section 2 of the Act(d), and includes the Gene Therapy Advisory Committee.

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

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

(a) to facilitate—

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

(ii) where relevant 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 relevant health research with persons or bodies (including by entering into agreements or memoranda of understanding), including the Administration of Radioactive Substances Advisory Committee(e), the Human Fertilisation and Embryology Authority(f), the Medicines and Healthcare Products Regulatory Agency(g) 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. Section 7 has been amended by section 21 of the Health and Social Care Act 2012 (c.7) ("the 2012 Act"). Section 8 has been amended by section 55(1) and 179(6) of, and paragraph 5(1) of Schedule 4 to, and paragraphs 1 and 3 of Schedule 14 to, the 2012 Act.

(b) The Health Research Authority is established by the Health Research Authority (Establishment and Constitution) Order 2011 (S.I. 2011/2323, amended by S.I. 2012/1109).

(c) Paragraph 13 of Schedule 1 was substituted by section 17(2) and (13) of the 2012 Act.

(d) Section 2 was substituted by section 55(1) of, and paragraph 1(1) of Schedule 4 to, the 2012 Act.

(e) 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.

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

(g) 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, 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 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(**d**), 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 of Health, Social Services and Public Safety for Northern Ireland, in the exercise of its functions;

(f) to co-operate with bodies that appoint Research Ethics Committees, 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 relevant health research matters;

(h) on behalf of the Secretary of State, to approve the processing of confidential patient information for medical purposes in the case of medical research, under regulation 5(a) of the Health Service (Control of Patient Information) Regulations 2002(**e**); and

(i) to appoint a committee of the Authority which must consist of persons who are not employees or members of the Authority, for the purpose of advising the Authority on the exercise of its functions under sub-paragraph (h) and for the purpose of carrying out the functions of the Authority under direction 5.

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

3. The Secretary of State, with a view to the Authority protecting and promoting the interests of patients and the public in relevant health research, directs the Authority to exercise the following functions in connection with establishing Research Ethics Committees and appointing members of Research Ethics Committees—

(a) to establish, as necessary and expedient in view of demand for the review of the ethics of relevant 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 relevant 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 relevant 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 relevant health research; or

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

(a) Established by section 1 of the Health and Social Care Act 2008 c. 14.
(b) Established by section 252(1) of the Health and Social Care Act 2012.
(c) Established by section 13 of the Human Tissue Act 2004 c. 30.
(d) 1998 c. 29.
(e) S.I. 2002/1438, amended by S.I. 2004/1031 and S.I. 2005/1622.

(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 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 which it has appointed 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

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(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.

(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.

Annual Reports

4. The Authority must prepare an annual report in relation to its activities and send a copy of its report to the Secretary of State by 30th November in the financial year following the financial year to which the report relates.

Functions of the Authority relating to advice to the Secretary of State in relation to the exercise of functions under the Health Service (Control of Patient Information) Regulations 2002

5. The Secretary of State directs the Authority to provide advice to the Secretary of State, in relation to the exercise by the Secretary of State of the Secretary of State's functions under regulations 2, 3(4) and 5(b) of the Health Service (Control of Patient Information) Regulations 2002.

Revocations

6. The Health Research Authority Directions 2011(a) and the Health Research Authority Amendment Directions 2012(b) are revoked.

Signed by authority of the Secretary of State for Health

28th March 2013

David Cox
Member of the Senior Civil Service
Department of Health

(a) These Directions were signed on 1st December 2011.
(b) These Directions were signed on 24th May 2012.