Care Act 2014

2014 CHAPTER 23

PART 3

HEALTH

CHAPTER 2

HEALTH RESEARCH AUTHORITY

Establishment

109 The Health Research Authority

(1) There is to be a body corporate called the Health Research Authority (referred to in this Act as "the HRA").

(2) Schedule 7 (which includes provision about the HRA's constitution, the exercise of its functions and its financial and reporting duties) has effect.

(3) The Special Health Authority called the Health Research Authority is abolished; and, in consequence of that, the following are revoked—

(a) the Health Research Authority (Establishment and Constitution) Order 2011 (S.I. 2011/2323), and

(b) the Health Research Authority Regulations 2011 (S.I. 2011/2341).

(4) The Secretary of State may by order provide for the transfer of property, rights and liabilities from that Special Health Authority to the HRA; for further provision about an order under this section, see section 118.

General functions

110 The HRA's functions

(1) The main functions of the HRA are—

(a) functions relating to the co-ordination and standardisation of practice relating to the regulation of health and social care research (see section 111);

(b) functions relating to research ethics committees (see sections 112 to 115);

(c) functions as a member of the United Kingdom Ethics Committee Authority (see section 116 and the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031));

(d) functions relating to approvals for processing confidential information relating to patients (see section 117 and the Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1438)).

(2) The main objective of the HRA in exercising its functions is—

(a) to protect participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical, and

(b) to promote the interests of those participants and potential participants and the general public by facilitating the conduct of research that is safe and ethical (including by promoting transparency in research).

(3) Health research is research into matters relating to people's physical or mental health; but a reference to health research does not include a reference to anything authorised under the Animals (Scientific Procedures) Act 1986.

(4) Social care research is research into matters relating to personal care or other practical assistance for individuals aged 18 or over who are in need of care or assistance because of age, physical or mental illness, disability, pregnancy, childbirth, dependence on alcohol or drugs or other similar circumstances; and "illness" has the meaning given by section 275(1) of the National Health Service Act 2006.

(5) A reference to health or social care research does not include a reference to research into matters which are within the legislative competence of a devolved legislature.

(6) A reference to research that is ethical is a reference to research that conforms to generally accepted ethical standards.

(7) Promoting transparency in research includes promoting—

(a) the registration of research;

(b) the publication and dissemination of research findings and conclusions;

(c) the provision of access to data on which research findings or conclusions are based;

(d) the provision of information at the end of research to participants in the research;

(e) the provision of access to tissue used in research, for use in future research.

(8) The Secretary of State may by order amend subsection (1) in consequence of—

(a) functions being given to the HRA,

(b) functions being taken away from the HRA, or

(c) changes to the description of functions that the HRA has for the time being.

Regulatory practice

111 Co-ordinating and promoting regulatory practice etc.

(1) The HRA and each of the following must co-operate with each other in the exercise of their respective functions relating to health or social care research, with a view to co-ordinating and standardising practice relating to the regulation of such research—

(a) the Secretary of State;

(b) the licensing authority for the purposes of the Medicines Act 1968;

(c) the Health and Social Care Information Centre;

(d) the Chief Medical Officer of the Department of Health;

(e) the Human Fertilisation and Embryology Authority;

(f) the Human Tissue Authority;

(g) the Care Quality Commission;

(h) the Administration of Radioactive Substances Advisory Committee;

(i) such person, or a person of such description, as regulations may specify.

(2) In performing the duty under subsection (1), a person must have regard to the need—

(a) to protect participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical, and

(b) to promote the interests of those participants and potential participants and the general public by facilitating the conduct of such research.

(3) The HRA must promote the co-ordination and standardisation of practice in the United Kingdom relating to the regulation of health and social care research; and it must, in doing so, seek to ensure that such regulation is proportionate.

(4) The HRA and each devolved authority must co-operate with each other in the exercise of their respective functions relating to the regulation of assessments of the ethics of health and social care research, with a view to co-ordinating and standardising practice in the United Kingdom relating to such regulation.

(5) The HRA must—

(a) keep under review matters relating to the ethics of health or social care research and matters relating to the regulation of such research, and

(b) provide the Secretary of State with such advice about the matters referred to in paragraph (a) as the Secretary of State requests.

(6) The HRA must publish guidance on—

(a) principles of good practice in the management and conduct of health and social care research;

(b) requirements, whether imposed by enactments or otherwise, to which persons conducting health or social care research are subject.

(7) A local authority (within the meaning of Part 1), an NHS trust established under section 25 of the National Health Service Act 2006 and an NHS foundation trust must each have regard to guidance under subsection (6).

(8) The ways in which persons may co-operate with each other under subsection (1) or (4) include, for example, by sharing information.

(9) Section 290 of the Health and Social Care Act 2012 (duties for health and social care authorities to co-operate), so far as applying to a person who is for the time being within subsection (1), does not apply to functions of that person relating to health or social care research.

(10) Section 110(5) (exclusion of research into matters within devolved competence) does not apply to the reference in subsection (1) or (4) to health and social care research.

Research ethics committees

112 The HRA's policy on research ethics committees

(1) The HRA must ensure that research ethics committees it recognises or establishes under this Chapter provide an efficient and effective means of assessing the ethics of health and social care research.

(2) A research ethics committee is a group of persons which assesses the ethics of research involving individuals; and the ways in which health or social care research might involve individuals include, for example—

(a) by obtaining information from them;

(b) by obtaining bodily tissue or fluid from them;

(c) by using information, tissue or fluid obtained from them on a previous occasion;

(d) by requiring them to undergo a test or other process (including xenotransplantation).

(3) For the purposes of subsection (1), the HRA—

(a) must publish a document (called "the REC policy document") which specifies the requirements which it expects research ethics committees it recognises or establishes under this Chapter to comply with, and

(b) must monitor their compliance with those requirements.

(4) The HRA may do such other things in relation to research ethics committees it recognises or establishes under this Chapter as it considers appropriate; it may, for example—

(a) co-ordinate their work;

(b) allocate work to them;

(c) develop and maintain training programmes designed to ensure that their members and staff can carry out their work effectively;

(d) provide them with advice and help (including help in the form of financial assistance).

(5) The requirements in the REC policy document may, for example, relate to—

(a) membership;

(b) proceedings;

(c) staff;

(d) accommodation and facilities;

(e) expenses;

(f) objectives and functions;

(g) accountability;

(h) procedures for challenging decisions.

(6) The HRA must ensure that the requirements imposed on research ethics committees in the REC policy document do not conflict with the requirements imposed on them by the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031).

(7) Before publishing the REC policy document, the HRA must consult—

(a) the devolved authorities, and

(b) such other persons as it considers appropriate.

(8) The HRA may revise the REC policy document and, where it does so, it must publish the document as revised; subsection (7) applies to a revised policy document in so far as the HRA considers the revisions significant.

(9) The HRA must indemnify the members of each research ethics committee it recognises or establishes under this Chapter against any liability to a third party for loss, damage or injury arising from the committee's exercise of its functions in assessing the ethics of health or social care research.

113 Approval of research

(1) The HRA must publish guidance about—

(a) the cases in which, in its opinion, good practice requires a person proposing to conduct health or social care research that involves individuals to obtain the approval of a research ethics committee recognised or established by the HRA under this Chapter, and

(b) the cases in which an enactment requires a person proposing to conduct research of that kind to obtain that approval.

(2) Before publishing guidance under subsection (1), the HRA must—

(a) consult the devolved authorities and such other persons as the HRA considers appropriate, and

(b) obtain the approval of the Secretary of State.

(3) The HRA may revise guidance under subsection (1) and, where it does so, it must publish the guidance as revised; subsection (2) applies to revised guidance in so far as the HRA considers the revisions significant.

(4) Schedule 8 (which amends various references to research ethics committees in secondary legislation) has effect.

114 Recognition by the HRA

(1) The HRA may, on an application made by or on behalf of a group of persons, recognise the group as a research ethics committee which is capable of—

(a) approving research of the kind referred to in section 113(1), and

(b) giving such other approvals as enactments require.

(2) The HRA may not recognise a group under this section unless it is satisfied that—

(a) the group will, if recognised, comply with the requirements set out in the REC policy document, and

(b) there is or will be a demand for such a group.

(3) In deciding whether to recognise a group under this section, the HRA must have regard to whether the group is recognised as a research ethics committee by or on behalf of a devolved authority.

(4) The HRA may do anything (including providing financial assistance) to help a group wishing to be recognised under this section to reach a position from which it should be able to make an application for recognition under this section that is likely to succeed.

(5) The HRA may revoke a recognition under this section if it is satisfied that—

(a) the group to which the recognition applies is not complying with the requirements specified in the REC policy document,

(b) the group is not (or is not properly) carrying out its function of assessing the ethical aspects of research, or

(c) revocation is necessary or desirable for some other reason.

(6) A group in existence immediately before the commencement of section 109, and established or recognised by or on behalf of the old Health Research Authority, or by or on behalf of the Secretary of State, as a research ethics committee which assesses health or social care research is to be regarded as recognised by the HRA under this section.

(7) The reference in subsection (6) to the old Health Research Authority is a reference to the Special Health Authority called the Health Research Authority (and abolished by section 109).

115 Establishment by the HRA

(1) The HRA may establish research ethics committees which have the following functions—

(a) approving research of the kind referred to in section 113(1);

(b) giving such other approvals as enactments require.

(2) The HRA must ensure that a research ethics committee established under this section complies with the requirements set out in the REC policy document.

(3) The HRA may abolish a research ethics committee established under this section.

116 Membership of the United Kingdom Ethics Committee Authority

In regulation 5 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) (United Kingdom Ethics Committee Authority)—

(a) in paragraphs (1), (2) and (3), for "the Secretary of State for Health", in each place it appears, substitute "the Health Research Authority", and

(b) in paragraph (2), for "the Secretary of State" substitute "the Health Research Authority".

Patient information

117 Approval for processing confidential patient information

(1) The Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1438) are amended as follows.

(2) In regulation 5 (the title to which becomes "Approval for processing information")—

(a) the existing text becomes paragraph (1), and

(b) in sub-paragraph (a) of that paragraph, for "both the Secretary of State and a research ethics committee" substitute "the Health Research Authority".

(3) After paragraph (1) of that regulation insert—

"(2) The Health Research Authority may not give an approval under paragraph (1)(a) unless a research ethics committee has approved the medical research concerned."

(4) After paragraph (2) of that regulation insert—

"(3) The Health Research Authority shall put in place and operate a system for reviewing decisions it makes under paragraph (1)(a)."

(5) In regulation 6 (registration requirements in relation to information), in paragraph (1)—

(a) before "the Secretary of State" insert "the Health Research Authority or", and

(b) before "he" insert "it or".

(6) In paragraph (2)(d) of that regulation, before "the Secretary of State" insert "the Health Research Authority or (as the case may be)".

(7) In paragraph (3) of that regulation, for the words from the beginning to "in the register" substitute "The Health Research Authority shall retain the particulars of each entry it records in the register, and the Secretary of State shall retain the particulars of each entry he records in the register,".

(8) For paragraph (4) of that regulation substitute—

"(4) The Health Research Authority shall, in such manner and to such extent as it considers appropriate, publish entries it records in the register; and the Secretary of State shall, in such manner and to such extent as he considers appropriate, publish entries he records in the register."