# Care Act 2014

**2014 CHAPTER 23**

**PART 3** U.K.

HEALTH

**CHAPTER 2** U.K.

HEALTH RESEARCH AUTHORITY

*Research ethics committees*

### 112 The HRA's policy on research ethics committees U.K.

(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.

**Commencement Information**

**I1** S. 112 in force at 1.1.2015 by S.I. 2014/2473, **art. 5(d)**

## 113 Approval of research U.K.

(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.

**Commencement Information**

**I2** S. 113 in force at 1.1.2015 by S.I. 2014/2473, **art. 5(e)**

## 114 Recognition by the HRA U.K.

(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).

**Commencement Information**

**I3** S. 114 in force at 1.1.2015 by S.I. 2014/2473, **art. 5(f)**

## 115 Establishment by the HRA U.K.

(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.

**Commencement Information**

**I4** S. 115 in force at 1.1.2015 by S.I. 2014/2473, **art. 5(g)**

## 116 Membership of the United Kingdom Ethics Committee Authority U.K.

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 ".

**Commencement Information**

**I5** S. 116 in force at 1.1.2015 by S.I. 2014/2473, **art. 5(h)**

**Status:**
Point in time view as at 01/01/2015.

**Changes to legislation:**
Care Act 2014, Cross Heading: Research ethics committees is up to date with all changes known to be in force on or before 27 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.