



Care Act 2014

2014 CHAPTER 23

PART 3

HEALTH

CHAPTER 2

HEALTH RESEARCH AUTHORITY

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.

Status: This is the original version (as it was originally enacted).

- (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.