



Care Act 2014

2014 CHAPTER 23

PART 3

HEALTH

CHAPTER 2

HEALTH RESEARCH AUTHORITY

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;
 - [^{F1}(c) NHS England, but only insofar as its functions relating to health or social care research are relevant data functions (as defined by section 253(3) of the Health and Social Care Act 2012);]
 - (d) the Chief Medical Officer of the Department of Health [^{F2}and Social Care];
 - (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—

Changes to legislation: Care Act 2014, Cross Heading: Regulatory practice is up to date with all changes known to be in force on or before 25 April 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. (See end of Document for details) View outstanding changes

- (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.

Textual Amendments

- F1** S. 111(1)(c) substituted (1.2.2023) by [The Health and Social Care Information Centre \(Transfer of Functions, Abolition and Transitional Provisions\) Regulations 2023 \(S.I. 2023/98\)](#), reg. 1(2), **Sch. para. 18(2)** (with reg. 3)
- F2** Words in s. 111(1)(d) inserted (11.4.2018) by [The Secretaries of State for Health and Social Care and for Housing, Communities and Local Government and Transfer of Functions \(Commonhold Land\) Order 2018 \(S.I. 2018/378\)](#), art. 1(2), **Sch. para. 16** (with art. 14)

Commencement Information

- I1** S. 111 in force at 1.1.2015 by [S.I. 2014/2473](#), art. 5(c)

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Changes and effects yet to be applied to the whole Act associated Parts and Chapters:

Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- s. 15(2)-(3B) substituted for s. 15(2)(3) by [2022 c. 31 s. 166\(2\)](#)
- s. 26(1)-(2A) substituted for s. 26(1)(2) by [2022 c. 31 s. 166\(4\)](#)