These notes refer to the Care Act 2014 (c.23) which received Royal Assent on 14 May 2014

CARE ACT 2014

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 3 - Health

Chapter 2 – Health Research Authority

Regulatory practice

Section 111 – Co-ordinating and promoting regulatory practice etc.

696. *Subsection (1)* imposes an obligation on the HRA and the people and bodies listed to co-operate with each other. The aim of this subsection is to encourage co-ordination and standardisation of practice of such bodies and persons when carrying out functions relating to the regulation of health and social care research. *Subsection (2)* provides that when exercising the duty to co-operate the HRA and specified people and bodies must have regard to the need to protect participants in health and social care research and the general public by encouraging safe and ethical research as well as promoting the interests of those people by facilitating the conduct of such research.

697. For example, the Secretary of State has both a duty to promote research in relation to the health service under section 1D of the National Health Service Act 2006 (the 2006 Act) and a power under paragraph 13 of Schedule 1 to the 2006 Act to conduct, commission or assist the conduct of research into any matters relating to the causation, prevention, diagnosis or treatment of illness, and research into any other matters connected with a service provided under the 2006 Act. The Secretary of State currently relies on these provisions to establish the National Institute for Health Research (NIHR) which funds research and the infrastructure to support research. As part of this role, the NIHR seeks to promote and coordinate proportionate research management systems within the NHS. Subsection (1)(a) requires the Secretary of State to work cooperatively with the HRA in relation to functions such as that of the NIHR.

698. The references to the Secretary of State and the licensing authority in subsection (1)(a) and (b) ensure that functions carried out by the Medicines and Healthcare Products Regulatory Executive Agency fall within the duty to co-operate. The reference to the Chief Medical Officer in subsection (1)(d) ensures that the Chief Medical Officer's function of receiving abortion notifications under regulation 4(1) of the Abortion Regulations 1991 (made under section 2 of the Abortion Act 1967) is covered by the duty.

699. There is a power to add to the list of the HRA's co-operation partners by way of regulations under subsection (1)(i). This may be used to include bodies that have relevant health and social care research functions conferred upon them in the future.

700. *Subsection (3)* imposes a freestanding duty on the HRA only to promote the co-ordination and standardisation of practice in relation to the regulation of health and social care research giving it the lead role in removing duplication and streamlining the regulation of health and social care research across the regulatory system. This is in addition to the reciprocal duty on HRA and the other bodies listed in subsection (1) to

co-operate with each other in this particular area insofar as their respective functions relate to the regulation of health and social care research. One way in which the HRA might meet this duty could be by continuing to run an integrated research application system (IRAS) currently administered by the HRA SpHA and by building on it to create a unified approvals process for research. The IRAS enables a researcher to enter information about their project into one application form which includes the information required for a number of different research approvals by different bodies.

701. *Subsection (4)* imposes an obligation on the HRA and the devolved authorities to co-operate with each other in the exercise of their functions where they relate to the regulation of assessments of the ethics of health and social care research, with a view to coordinating and standardising practice in the United Kingdom relating to the regulation of such research. Health and social care research in this context includes research that relates to the functions exercisable by a devolved authority or which is within the legislative competence of the devolved legislature (*subsection (10)*).

702. *Subsection (5)* requires the HRA to undertake a horizon scanning function to keep under review matters relating to the ethics of health and social care research and to advise the Secretary of State about such matters if requested.

703. The Department of Health currently publishes the Research Governance Framework for Health and Social Care which sets out the broad principles for good research governance. *Subsection (6)* requires the HRA to publish guidance on principles of good practice in the conduct and management of health and social care research, and any requirements imposed upon researchers in legislation or by other sources.

704. Under *subsection (7)*, a local authority, an NHS trust in England and an NHS foundation trust must have regard to guidance published under subsection (6).

705. *Subsection (8)* makes express provision that co-operation under subsection (1) or (4) can include sharing information.