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

Establishment

Section 109 – The Health Research Authority

664. This section establishes a new body to be known as the Health Research Authority (HRA). The HRA is to have functions relating to health and social care research which are conferred in other sections in this chapter.

665. The HRA is to replace the Special Health Authority (SpHA) also known as the Health Research Authority and take on its functions, which include those relating to reviewing the ethics of research proposals in England. Like the SpHA, the HRA will have the objective of protecting and promoting the interests of actual and potential participants in health and social care research and the general public by facilitating and promoting high quality research that is safe and ethical. *Subsection (3)* abolishes the SpHA and the relevant instruments establishing it and conferring functions on it. *Subsection (4)* makes provision for the Secretary of State to make an order to transfer the property, rights and liabilities from the SpHA to the HRA.

Schedule 7 –The Health Research Authority

666. This Schedule makes provision for the constitution and establishment of the HRA.

Part 1 – Constitution

667. *Paragraph 1* makes provision about the membership of the HRA. The Board will be made up of a chair, three or four non-executive members, a chief executive and two or three executive members.

668. *Paragraph 2* makes provision about the terms of appointment and tenure of office of non-executive members. Sub-paragraph (2) specifies that the maximum term for a non-executive is 4 years. Sub-paragraph (3) specifies that a person who ceases to be a non-executive member is eligible for re-appointment. Provision is made in sub-paragraph (4) to enable a non-executive member to resign at any time by giving notice to the Secretary of State, and sub-paragraphs (5) and (6) enable the Secretary of State to remove or suspend non-executive members from office on the grounds of incapacity, misbehaviour or failure to carry out his or her duties as a non-executive member.

669. *Paragraph 3* sets out the procedural requirements to be complied with where the Secretary of State suspends a non-executive member of the HRA under the power in paragraph 2(6).

670. *Paragraph 4* enables the Secretary of State to appoint a non-executive member as interim chair where the chair is suspended under paragraph 2(6), and sets out the conditions that apply to that appointment.

671. *Paragraph 5* requires the HRA to make payments to the non-executive members and the chair. The level of these payments would be determined by the Secretary of State.

672. *Paragraph 6* gives the HRA powers to appoint employees on such terms as it may determine. The appointment of the chief executive must be agreed by the Secretary of State.

673. *Paragraph 7* allows the HRA to decide the levels of pay, pensions or allowances it will make to its staff. In line with other arms-length bodies (for example, Monitor, Care Quality Commission, NHS Commissioning Board (known as NHS England) and, as covered by this Act, HEE), the HRA would be required to seek the approval of the Secretary of State to its policy on pay, pensions and allowances.

674. *Paragraph 8*makes provision about the appointment of committees and sub-committees by the HRA. Sub-paragraph (1)(a) and (b) requires the HRA to appoint a committee to advise the HRA and the Secretary of State in relation to their respective functions under the Health Service (Control of Patient Information) Regulations 2002. The advice to be given under sub-paragraphs (1)(a) and (1)(b) includes advice on applications to process confidential patient information for medical purposes to the HRA in the case of medical research and to the Secretary of State in other cases.

675. Sub-paragraph (1)(c) requires the committee to advise the Health and Social Care Information Centre. The committee would supply advice in connection with HSCIC's exercise of functions pursuant to further regulations under section 251 of the 2006 Act, and also in connection with any publication or other dissemination by HSCIC of information which identifies an individual or could potentially be used to identify an individual.

676. Sub-paragraph (3) requires the committee under sub-paragraph (1) to consist of persons independent of the HRA. Sub-paragraph (2) enables the HRA to appoint other committees and sub-committees. Committees appointed under paragraph 8 can include participants in research, potential participants and the public as well as any persons with particular expertise relevant to the committee's work, for example, nurses or social workers or any other person HRA considers appropriate. The HRA may pay members of its committees where they are not employees of the HRA.

677. *Paragraph 9* provides a power to set out in regulations the specific factors or matters to which the committee appointed by the HRA under paragraph 8(1) of Schedule 7 must have regard when advising on the exercise by:

- the HRA or the Secretary of State of functions under the Health Service (Control of Patient of Patient Information) Regulations 2002, or
- the HSCIC of functions pursuant to further regulations under section 251 of the 2006 Act or any publication or other dissemination by the HSCIC of information which identifies or could be used to identify an individual.

Such factors or matters might include the need to ensure processing must respect and promote patient privacy and that an applicant for access to such information has not breached confidentiality in the past.

678. *Paragraph 10* allows the HRA to regulate its own procedure. So for example, this power may enable the HRA to remove the risk of a conflict of interest by preventing executive members from being involved in determining their own pay. Sub-paragraph (2) provides that a vacancy amongst the members of the HRA or a defect in appointment of a member does not prevent the HRA from continuing to operate.

679. *Paragraph 11* makes provision in relation to the HRA's seal which would be used to show approval of official HRA documents.

680. *Paragraph 12* provides that the status of the HRA would be a non-departmental public body that is not part of the Crown, nor regarded as a servant or agent of the Crown.

Part 2 - Functions

681. *Paragraph 13* places a requirement on the HRA to exercise its functions effectively, efficiently and economically. Provision is made to enable the HRA to arrange for any person to exercise on its behalf, or assist with the exercise of its functions and to make payments to them. Sub-paragraph (5) gives the HRA a general power to do anything which appears to it to be necessary or desirable for the purpose of, or in connection with the exercise of its functions.

682. *Paragraph 14*(1) makes provision for the HRA to provide help or advice to another public authority (as defined in sub-paragraphs (3) and (4)) for the purpose of the exercise of functions by that public authority to meet its objectives. By way of example, it is envisaged that this power could be used to enable HRA to advise and assist the Human Fertilisation and Embryology Authority in relation to applications to process information under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 (S.I. 2010/995). Sub-paragraph (2) makes provision for the HRA to determine the terms under which it provides the help or advice in sub-paragraph (1), including rates of pay and allowances.

683. *Paragraph 15* enables Scottish Ministers, Welsh Ministers, or the Department of Health, Social Services and Public Safety in Northern Ireland to arrange for the HRA to exercise certain functions. These are those functions which relate to health or social care research and correspond to a function of the HRA, or to provide services or facilities to them in connection with the exercise of such functions. Sub-paragraph (2) makes express provision to enable the parties to agree for the HRA to receive payments to recoup its costs.

684. If the Secretary of State considers that the HRA is failing or has failed to exercise its functions, and the failure is significant, *paragraph 16*(1) would give the Secretary of State the power to direct the HRA to perform its functions. If the HRA fails to comply with the direction made under sub-paragraph (1), sub-paragraph (2) would enable the Secretary of State to exercise the functions specified in the direction, or make arrangements for another person to exercise those functions on his behalf. Where the Secretary of State exercises the power under sub-paragraph (1) or (2), he must publish the reasons for doing so

Part 3 – Finance and reports

685. *Paragraph 17* makes provision for the Secretary of State, with the consent of the Treasury, to make payments to the HRA. The payments could be made at any time and have any conditions attached to them which the Secretary of State considers appropriate.

686. *Paragraph 18* gives the Secretary of State the power to make regulations requiring a fee to be paid to the HRA for specified functions. Any regulations made under this section would be subject to the affirmative parliamentary procedure. Any fees prescribed under this section, as determined by the HRA, would need to take account of the cost of the functions involved and must be approved by the Secretary of State.

687. Paragraph 18(7) applies existing legislation so that the members and staff of HRA are protected from personal liability whilst carrying out work on behalf of HRA. Paragraph 17(9) amends section 71 of the National Health Service Act 2006 to add the HRA to the list of bodies that may join a scheme established by the Secretary of State for the purpose of meeting expenses arising from any loss, damage or injury incurred by members, to

their property and liabilities, and to third parties for loss damage or injury arising out of carrying out the functions of the bodies.

688. *Paragraph 19*(1) requires the HRA to keep accounts and prepare annual accounts for each financial year in a form to be determined by the Secretary of State, and which must be audited by the Comptroller and Auditor General.

689. *Paragraph 20* requires the HRA to prepare an annual report on the activities it has undertaken during the previous financial year and the activities it proposes to undertake during the current financial year. The report must include information about health and social care research which has taken place during the year as well as setting out the steps the HRA has taken to fulfil its objectives under section 110(2). The HRA must lay a copy of the report before Parliament and send a copy to the Secretary of State. Paragraph 19(4) provides that the HRA must provide the Secretary of State with other reports and information relating to the exercise of its functions on request.

Part 4 – Consequential amendments

690. *Paragraphs 21 to 27* make amendments to other primary legislation so that the relevant provisions apply to the HRA. For example, paragraph 23 amends Part 2 of Schedule 1 to the House of Commons Disqualification Act 1975 to insert the HRA into the list of bodies whose members are disqualified from membership of the House of Commons.

General functions

Section 110 – The HRA's functions

691. *Subsection (1)* sets out the HRA's main functions. These functions relate to the co-ordination and standardisation of practice relating to the regulation of health and social care research, research ethics committees, membership of the United Kingdom Ethics Committee Authority under the Medicines for Human Use Clinical Trials) Regulations 2004 (Clinical Trials Regulations), and the process for approving the processing of confidential patient information for medical research. The functions are set out in detail in sections 109 to 115.

692. *Subsection (2)* sets out the main objective of the HRA when performing its functions to:

- protect participants and potential participants in health and social care research and the general public by encouraging safe and ethical research which conforms to generally accepted ethical standards as described in *subsection (6)*; and
- promote their interests by facilitating the conduct of research which is safe and ethical. This includes by promoting transparency in research. *Subsection (7)* lists some of the ways in which transparency in research can be promoted, for example, by promoting the publication and dissemination of research findings and conclusions.

693. Therefore, for example, in carrying out its duty to cooperate with other bodies that hold research related functions the HRA would need to act in a way that will ensure that people are protected through safe and ethical standards whilst also facilitating research. This might involve, for example, removing duplication and ensuring proportionate regulation.

694. *Subsection (3)* defines health research as research into matters relating to people's physical or mental health. The definition does not include health research involving animals that is regulated by the Animals (Scientific Procedures) Act 1986. *Subsection (4)* defines social care research as 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 for any of the reasons listed. The definitions of health research and social care research are not restricted to any particular professional group so, for example, they would include nurse-led research. The references to health or social care research in this

chapter do not, except where otherwise stated, include research into matters which are within the legislative competence of the devolved legislature (the Scottish Parliament, the National Assembly for Wales or the Northern Ireland Assembly) (*subsection (5)*).

695. *Subsection (8)* provides a power to amend by order the list of functions in subsection (1) in consequence of functions being given to or taken away from the HRA or amended by other statutory enactments.

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.

Research ethics committees

Section 112 – The HRA's policy on research ethics committees

706. This section states the general policy of the HRA in relation to research ethics committees (RECs) it recognises or establishes under sections 114 and 115. The HRA needs to ensure that RECs provide an efficient and effective means of assessing the ethics of health and social care research. *Subsection (4)* sets out ways in which the HRA may fulfil this function, such as co-ordinating and allocating work to RECs, and providing help and advice. The HRA may also develop and maintain a training programme to ensure that RECs' members and staff can carry out their work effectively. *Subsection (9)* requires the HRA to indemnify members of the RECs against certain risks that may be involved in the exercise of the committees' functions in assessing the ethics of health and social care research.

707. RECs are defined by *subsection (2)* as a group which assesses the ethics of research involving individuals and gives examples of how research may involve individuals, including obtaining information, tissue or fluid from them.

708. *Subsection (3)* requires the HRA to publish a REC policy document to set out the requirements that RECs recognised or established by the HRA would be expected to comply with and must monitor their compliance. These requirements are currently set out in the Governance arrangements for RECs (GAfREC) document published by the Department of Health. *Subsection (5)* lists the requirements that may be included in the REC policy document. *Subsection (6)* requires the HRA to ensure that the requirements in the REC policy document do not conflict with the requirements imposed on ethics committees under the Clinical Trials Regulations. The Clinical Trials Regulations establish a body called the United Kingdom Ethics Committee Authority (UKECA) which has the power to establish and recognise ethics committees for the purpose of approving clinical trials on investigational medicinal products for human use in the UK under the Clinical Trials Regulations. This subsection would enable a committee which is recognised or established by the HRA also to be able to meet the requirements for recognition by UKECA to ethically approve clinical trials of investigational medicines under the clinical trials regulations so as to avoid duplication. *Subsection (8)* allows the HRA to revise the document.

709. *Subsection (7)* requires the HRA to consult the devolved authorities and anyone else it considers appropriate on the content of the document before it is published. This also applies to any significant revision of the document made under subsection (8).

Section 113 – Approval of research

710. At present the Department of Health issues policy guidance on RECs (the GAfREC document) which sets out when the Department considers it is good practice or legislation requires them to seek approval of research by a REC, or where legislation requires the researcher to do so. *Subsection (1)* of this section requires the HRA to publish guidance setting out when it considers it good practice to seek approval of research by a REC.

711. *Subsection (2)* requires the HRA to consult the devolved authorities and other people it considers appropriate, and obtain approval of the Secretary of State before publishing guidance. Where the HRA revises its guidance, and it considers the revisions significant, it must consult and seek approval from the Secretary of State before publishing the revised guidance (*subsection (3)*).

712. *Subsection (4)* introduces Schedule 8, which contains amendments relating to references to RECs in secondary legislation.

Schedule 8 – Research ethics committees (RECs): amendments

713. Schedule 8 makes consequential amendments to secondary legislation where references are made to RECs. The amendments replace references to ethics committees recognised by the Secretary of State with reference to those established or recognised by the HRA. The amendments also standardise the definitions of RECs to bring them into line with the definition of a REC under section 112.

Section 114 – Recognition by the HRA

714. This section makes provision for the HRA, following an application by or on behalf of a group of people, to recognise that group as a REC for the purpose of approving research of a type specified by the HRA in the guidance issued under section 113(1) or for the purpose of approving research where this is required under other legislation.

715. Under *subsection (2)* the HRA would only be able to recognise a REC if it is satisfied that the REC meets the requirements of the REC policy document published by the HRA under section 112*(3)*, and that there is, or will be, a demand for such a group. *Subsection (3)* would require the HRA to take into consideration whether the group is already recognised as a REC by, or on behalf of, a devolved authority. *Subsection (4)* enables the HRA to do anything (including provide financial assistance) to help a group of people who want to be recognised to make an application which is likely to be successful. Therefore, for example the HRA may consider it appropriate to make a meeting room available to a REC in which they can conduct their business.

716. *Subsection (5)* gives the HRA the power to revoke recognition of a REC where it is satisfied that the recognised REC is not complying with the requirements of the REC policy document published by the HRA under section 112(3). Recognition may also be revoked if the HRA is satisfied that the group is not carrying out its function of assessing the ethical aspects of research, or is not doing so properly, or that the revocation is necessary or desirable for another reason.

717. Any group which was established or recognised by the SpHA Health Research Authority or by the Secretary of State as a REC, and which exists when the new provisions come into force would, under *subsection (6)*, receive automatic recognition by the HRA.

Section 115 – Establishment by the HRA

718. This section gives the HRA the power to establish RECs for the purpose of approving research of the type specified by the HRA in the guidance document issued under section 113(1), or giving such other approvals as are required. The HRA would be required, under *subsection (2)*, to ensure that any REC it establishes complies with the requirements in the REC policy document. Therefore, for example, if the guidance sets out requirements for lay membership, the REC must comply. *Subsection (3)* provides that the HRA has the power to abolish a REC it has established under this section.

Section 116 – Membership of the United Kingdom Ethics Committee Authority

719. This section amends regulation 5 of the Clinical Trials Regulations which provides for the membership of the United Kingdom Ethics Committee Authority (UKECA) to replace the Secretary of State's membership with that of the HRA and makes other amendment consequential on this change.

Patient Information

Section 117 – Approval for processing confidential patient information

720. This section makes a number of amendments to the Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1438) (the 2002 Regulations). These amendments transfer the Secretary of State's power to approve the processing of confidential patient information for research purposes to the HRA and change the way that the requirement for REC approval is expressed legally. These changes will retain the safeguards currently in place.

721. *Subsection (2)* amends regulation 5 of the 2002 Regulations to replace the requirement for approval from the Secretary of State and a REC for the processing of confidential patient information for the purpose of medical research, with a requirement for approval only from the Health Research Authority (new regulation 5(1)(a)). *Subsection (3)* inserts new sub-paragraph (2) into regulation 5 of the 2002 Regulations which provides that the HRA may not give approval under new paragraph 5(1)(a) unless a REC has approved the medical research concerned. This means that approval for processing confidential patient information for the purpose of medical research would require approval by the HRA as well as REC approval of the ethical aspects of the research concerned.

722. *Subsection (4)* inserts new sub-paragraph (3) into regulation 5 of the 2002 Regulations to require the HRA to put in place a system for reviewing decisions it makes in relation to the processing of patient information under sub-paragraph (1)(a).

723. *Subsections (5) to (8)* amend regulation 6 of the 2002 Regulations to require the HRA to record in a register details about any transfer of information which is approved under the regulations. Provision is also made to require the HRA to retain such information and to enable it to publish any entries in the register, as it considers appropriate.