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

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.