

# CARE ACT 2014

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## EXPLANATORY NOTES

### COMMENTARY ON SECTIONS

#### **Part 3 - Health**

#### *Chapter 2 – Health Research Authority*

#### **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.