

Retrospective Chart Review Studies: Position agreed by the Department of Health with the Data Protection Commission pending the making of a formal amendment which is expected in early October.

The requirement for explicit consent in the Health Research Regulations will not apply in relation to a retrospective chart review study to be carried out by a controller and approved by a research ethics committee where the REC states in its approval that the required assessment carried out by the controller of the data protection implications of the processing of the personal data being processed in the research does not indicate a high risk to the rights and freedoms of data subjects.

The above applies only where the retrospective chart review study is carried out on behalf of the controller by-

- (a) a health practitioner employed by the controller or a person studying to be a health practitioner who is under the direction and control of the controller,
- or
- (b) an employee of the controller (other than a health practitioner in subparagraph (a)) who, in the course of his or her duties for the controller, would ordinarily have access to the personal data of individual held by the controller that was obtained for the provision of health care to those individuals.

Where the controller intends to carry out a retrospective chart review study, the arrangements by the controller to ensure that personal data are processed in a transparent manner must

include appropriate notices and posters on display in public areas of the data controller's organisation stating that-

(a) personal data collected by the controller for the provision of health care to an individual may be used but not disclosed to another person by the controller for the study,

(b) any findings from a study that are published shall not identify an individual whose personal data was used in the study, and

(c) a study will be reviewed and approved by a research ethics committee prior to commencement of the study.

A 'retrospective chart review study' means a health research study carried out by a controller on personal data for the purposes of health research that has already been obtained by that controller for the purposes of the provision of health care to an individual by the controller.

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