

CENTRAL ETHICAL REVIEW BOARD

26 May 2008

Concerning changes made to the Act (2003:460) concerning the Ethical Review of Research Involving Humans (the ethical review act) etc

As a result of SFS 2008:192, a number of changes have been made to the Ethical Review Act. These changes came into force on 1 June 2008.

As a consequence of one of the changes, a new definition of the concept of research has been introduced into section 2. According to the new wording "research" is understood to mean not only scientific, experimental or theoretical work to obtain new knowledge, but also developmental work carried out on a scientific basis, with the exception of that which is carried out as part of a programme of study at an institute of higher education at a basic or advanced level.

It transpires that the new definition has given rise to certain problems of interpretation. The Central Ethical Review Board wishes to point out that in this context "theoretical work" must be intended to include non-experimental observational research of various kinds, such as descriptive and analytical epidemiological research or other research not involving intervention (including research in the course of which treatment is carried out) which is accomplished with the help of registers, interviews and questionnaires.

In addition, the changes to the legislation mean that all research that comprises treatment of so-called sensitive personal information is to be subject to an ethical review, whether or not the subject of the research has explicitly given their consent.

Moreover, it must be pointed out that while it is true that such work as is carried out by a student within the framework of a programme of study at an institute of higher education at a basic or advanced level does not need to be reviewed according to the provisions of the ethical review act, a regional review board may, at the request of the applicant, give an advisory statement concerning such work.

(This addition to the Statute (2003:615) concerning the Ethical Review of Research Involving Humans, came into force on 1 July 2008).