

Memorandum

Amendment 1 June 2008

Note the Central Ethical Review Boards letter “Concerning changes made to the Act (2003:460) concerning the Ethical Review of Research Involving Humans (the ethical review act) etc” – (e.g. a new definition of the concept of research has been introduced into section 2).

The usage of the concept of research by the Central Ethical Review Board

Defining the concept of research.

Ethical review is only applicable where the issue of research on human beings is concerned. If a project does not involve research, the statute is not applicable and an application for approval will not be considered. Neither will any advisory statement be issued in such cases.

In section 2 of the Ethical Review Act, "research" is defined as "scientific research and developmental work on a scientific basis".

The definition is not particularly explanatory and changes are proposed in government report SOU 2005:78. The definition proposed in the report is more logical and worked out in more detail, but in practice is unlikely to make evaluations any easier.

The tasks of the ethical review boards

In most cases that have been subjected to ethical review, the question as to whether any particular project constitutes research has not been specifically dealt with as an issue. When the concept of research is discussed in this context, one should also bear in mind that it has in no way been deemed to be the principal task of the ethical review boards to decide what does or does not constitute research. The organisation of the boards and the ethical review act came into being in order to ensure that a research project does not entail disproportionate risks or inconvenience with respect to the gains in knowledge resulting from the project.

Reviews of this nature should naturally be carried out even when it is a question of a project that cannot be deemed to be research. The review could devolve to teachers or the doctor responsible or heads of units, for example. However, it is not intended that the skills of the board organisation that has been built up and which involves the collaboration of the community of researchers should be called upon when the issue involved is something other than research.

The principle is thus designed to place a limit upon the tasks allotted to the boards. In practice the result has to some extent been the contrary and the boards have devoted a great deal of effort to the issue of whether or not a particular project constitutes research. This is not really in line with the intentions of the act.

Scientific issues and scientific methods

There are a number of definitions that are more illuminating than the one which is to be found in the ethical review act. Irrespective of the definition one may wish to use, it should be obvious that use of the term "research" presumes that there is a scientific purpose, i.e. a relevant issue, *within the scientific field*, which it is intended to illuminate in a systematic manner or, if one so wishes, using scientific methods. This is, in principle, both a sufficient and necessary requirement in order for a project to be characterized as research. In addition, as will be considered in more detail shortly, it is also necessary that there be an intention to make the results accessible.

However, the question as to whether there is an issue within the field of science that it is intended to illuminate in an acceptable manner is not always so easy to answer. It has been pointed out previously that it was never the intent that the boards were to devote a great deal of effort to answering this question, which in practice is considered by many other institutions independently of the ethical review. The result can be almost absurd: for example, when a certain project has received research grants from the Swedish Research Council, on condition that approval is given after an ethical review, but the ethical review board refuses to carry out a review on the grounds that the board does not consider that the project constitutes research.

The precedents set by the work of the Central Ethical Review Board have led to certain guidelines for evaluating whether a project should be deemed to constitute research.

Presumptions

As a result, the Central Ethical Review Board has, in a considerable number of cases, maintained that a project should be intended to form the basis of a public defence of a doctoral thesis or otherwise form a part of a doctoral thesis or that the project is to be carried out by or under the guidance of qualified researchers. This should be interpreted to mean that the boards, unless there are quite exceptional reasons, are entitled under such circumstances to presume that there is a scientific issue which it is intended to illuminate in a systematic manner. Judging by the explanations given for their decisions, the presumption is particularly strong when the issue is that of a project which is to form the basis of a public defence of a doctoral thesis disputation. This is also quite natural: in such cases it must be presumed that the chosen arrangement has been carefully reviewed by another body and can be deemed to be research. This is also presumed in the legislative history of the ethical review act.

However, it cannot be correct to consider as a sufficient prerequisite the fact that it is the intention that a project is to be carried out either by qualified researchers or under the supervision of qualified researchers. One example among many of a different ruling being made is case Ö14-2006. This case refers to a series of studies, the design of which was randomised and controlled, and the aim of which was to compare the moisturising effect on the skin of certain cosmetic creams available in retail outlets. Admittedly the project was to be carried out under the guidance of a qualified researcher, but the Central Ethical Review Board ruled (not unanimously) that it was more a question of a comparative test of consumer products and was not a matter of scientific research. Another example is case Ö34-2005, in which a comparison test of the taste of various nicotine chewing gums was not deemed to be research. One might perhaps be able to interpret these decisions in such a way that the purpose was not deemed to be scientific by the majority of board members.

As for the requirement that the approach should be scientific: in several cases, for example case Ö17-2007, which was a highly controversial one, the board maintained that even though qualified researchers were involved, various projects did not contain any studies that differed from normal clinical routines and thus did not contain scientific elements. On the other hand, the requirement that there be a scientific or systematic method should not be interpreted in such a way as to mean that it should be impossible to lodge any objections against the design of it. It is clear from precedents set by the board that an application should be evaluated on its own terms and should not be rejected if the project consists of a scientific approach, even if powerful objections could be made against its design and the project quite simply is deemed unable to answer the question posed. However, a weakness of such nature in the scientific design when the review is carried out, could mean that the knowledge gained is deemed to be so little that when it is weighed against the possible risks and discomfort for people participating in the research, ethical considerations preclude acceptance.

As for the issue of work carried out by students as part of a course of undergraduate study, there is a presumption in the legislative history of the act that such work would not normally be subject to the legislation. Needless to say, such work should nonetheless be subject to ethical review when necessary, but according to the legislative history this should be done by the supervisors and by the institution responsible (government bill 2002/03:50 page 92). As a general rule the board has followed these guidelines. However, when this was done, the current organization with respect to masters degrees and breadth of subjects had not been developed and it is therefore somewhat uncertain if, when carrying out work which will result in such a qualification, one can have the same presumption. If the responsible supervisor decides that it is an issue of a thesis for a masters degree for which publication in a scientific periodical is possible or which can be expanded to form a doctoral thesis, it would seem that the board, as a rule, should consider the application for review. This has been done in case Ö9-2007, for example. One must however concede that in such cases it is particularly troublesome to draw the line.

A particular presumption applies in cases where the Swedish Medical Products Agency has ruled that a project constitutes the clinical testing of pharmaceutical products. It must therefore be deemed to follow from the pharmaceutical directives of the EU that the project must be subjected to ethical review and the legislation must therefore be interpreted in a way that satisfies the regulations of the EU. This entails that the boards must be deemed to be bound by the ruling of the Swedish Medical Products Agency and must presume that it is a question of research. Compare case Ö17-2007, in which the majority view was:

"Even though it is debateable whether this particular project constitutes research in the accepted sense of the word, it is the view of the Central Ethical Review Board, given the general obligation to give the legislation an interpretation in line with the directives, that the project must be considered to be subject to the Ethical Review Act."

The work of assessment

Demarcation becomes particularly difficult when a project includes quality assurance or the following up of results on a scientific basis. Regarding this issue of demarcation it has been said in the legislative history (government bill 2002/03:50 page 91):

"An issue of demarcation arises between scientific research and, for example, quality assurance and the following up of results. This proposed legislation is aimed at scientific

research. As a guideline for the demarcation that needs to be done, the following can be said. According to section 31 of The Health and Medical Service Act (1982:763), quality within the health care and medical services is to be systematically and continually developed and assured. Enterprises of this and a similar nature are not to be subject to ethical review according to the proposed legislation now being suggested. The ethical judgements that might need to be made as part of the activities of authorities concerning other matters than research may be investigated in a different way if this is deemed necessary. Sometimes scientific developmental work forms part of the work of authorities when follow-up and so forth is involved. If the purpose of scientific developmental work is the internal evaluation work of authorities, such developmental work should not be subject to ethical review according to the proposed legislation. What is decisive concerning the character of a project must naturally be decided from case to case, and the guidelines above should be able to provide guidance when this evaluation is made."

The board has taken notice of these statements and in practice primarily taken into account whether it is stated that the results of a project can be deemed to be intended for publication in a scientific journal. The point being that if the intention is to disseminate the results of the study in scientific publications outside the immediate health care and medical services field, the purpose logically cannot be said to be limited to the internal evaluation work of the authorities. It has then been judged to be research - developmental work on a scientific basis - if it in other respects fulfils the requirements needed for this. This applies even if the board cannot be given any guarantees that an article on the subject will be accepted by a publication in due course.

What the significance may be in other cases, if the applicant intends to make the results accessible by publication in a scientific journal, cannot be claimed to have been completely solved by precedents set by the board. There is a requirement with respect to the ethics of the research, that the result of any research should be made public. However, there may be acceptable reasons for making only parts of a study available: when a patent application is being prepared, for example.

Overall evaluation

These guidelines do not mean that in borderline cases an overall evaluation must be made in which several of the factors briefly touched on here must be weighed against each other.

One example among many of such an overall evaluation is illustrated by case Ö18-2005, which concerned a course for employees in so-called "empowerment", the purpose of which was to help patients to achieve changes in behaviour. The Central Ethical Review Board reversed the decision of the regional board and ruled that this did constitute research with the following motivation:

"There is no doubt that the project in question primarily has the character of a following up of results. However the Central Ethical Review Board has learned that the project, together with other work, will form the basis for a public defence of a doctoral thesis and that it will be conducted under the supervision of two qualified researchers. Given that background, the board is not prepared to state that scientific elements are lacking. Neither can the project be deemed to have the sole purpose of contributing to the internal evaluation work of the authority, since it is intended for all county councils via the training centre jointly used by all

county councils (LUCD). In addition the intention is that it will be published in scientific periodicals."

Summary

To sum up: on the basis of the practice of the board to date, one could say that in principle having a scientific question at issue and a scientific or systematic approach are necessary and sufficient prerequisites for a project to be deemed to comprise research. If the project is to form the basis for a public defence of a doctoral thesis, it can normally be presumed that these requirements are fulfilled. In addition, the circumstance that the project is to be conducted by qualified researchers is powerful confirmation that it is indeed a question of research. Where the work of students is concerned, the presumption is the opposite: this is not normally considered to be research.

At any rate, when it is an issue of an evaluation of methods of treatment, for example, which is something that authorities such as those in the field of health care and medical services have an obligation to conduct on an ongoing basis, it is necessary in addition that it is not merely an issue of work within an authority, but also that there is an intention to disseminate the results, by means of publication in a scientific journal, for example. Particularly in borderline cases an overall evaluation must be carried out.

According to EU legislation, projects which have been approved by the Medical Products Agency as the clinical testing of pharmaceuticals shall in principle always be deemed to constitute research.

This memorandum has been drawn up after discussions at a meeting of the Central Ethical Review Board on 8 October 2007.