

Background and regulations

There are a number of reasons why the ethical vetting of research involving individual human beings should be regulated by law. One reason is that people who participate in research as the subjects of such research, or something similar, should be protected against the risk of physical injury, mental injury or the violation of their integrity. To the extent that certain research can involve risks for the subjects of the research, there should be an investigation that includes, among other things, a weighing-up of the risks involved against the knowledge gained. High standards should be insisted upon with respect to the quality of the research and to ensure that the subjects involved have understood and accepted the conditions that apply to their participation. It is also legitimate for the general public to be given both insight into and influence upon the ethical vetting of research, since it is of general interest that human dignity should be protected and human integrity should be safeguarded. Regulation that is enforced by law and guarantees the participation of representatives of the general public in the process of ethical vetting should, in the long term, increase the confidence of the general public in research.

[...]

Protection for those participating in medical research has also been brought to the fore with the signing, by Sweden, of the European Council's Convention on Human Rights and Biomedicine. In order for Sweden to be able to ratify this convention, which contains certain stipulations concerning the conduct and implementation of ethical vetting, such vetting requires legally enforced regulation. Swedish legislation also needs to be adapted to the directive concerning the implementation of good clinical practice in the course of clinical trials of medicinal products for human use (2001/20/EG).

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