Dnr 10/02

Ministry of Health and Social Affairs
SE-103 33 Stockholm

March 25, 2002

Re: Draft additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research

As part of the ongoing national consultations regarding the draft additional protocol on biomedical research, the Swedish National Council on Medical Ethics wishes to state its opinion to the Swedish Ministry of Social Affairs, and thereby to the Steering Committee on Bioethics (CDBI). The Council is greatly appreciative of the continued efforts of the CDBI, and welcomes that an additional protocol on biomedical research is underway.

General comments

When considering the protocol, the Council has addressed the following questions:
Would the protocol ensure sufficient protection of the interests and welfare of the human beings participating in research, as well as of human dignity in a wider societal context?
Would the protocol put undue restrictions on potentially important biomedical research?
Is the protocol formulated in a fashion that would facilitate its incorporation into national legislations, or may problems arise for purely technical reasons?

The Council notes that the protocol does not apply to all human biomedical research, since research on embryos in vitro as well as on deceased persons is excluded. In some respects, the regulations are specified in great detail. This may create formal obstacles to research, without any obvious gains in protection, neither of the interests and welfare of the human beings participating in research, nor of human rights and dignity in a wider context. Examples are given below, as some of the articles are commented.

Comments on specific articles

Article 11 – Independent examinations by an ethics committee
According to article 11, the multidisciplinary examination of the ethics committee is limited to the protection of the research participant. However, in keeping with the Convention on Human Rights and Biomedicine the interests of a third party or society at large also require attention. The Convention and the present draft protocol clearly declare human rights and human dignity to be societal values that must never be compromised, but it is not made clear what sort of body or agency should consider these values in relation to biomedical research. It is the opinion of this Council that the ethics committees should be mandated to do so.

Article 13 – Information for the ethics committees and *Article 16 – Information for research participants*

The articles specify in great detail what information should be given to the ethics committees, and to the participants, respectively. A problem lies in the fact that not all conditions apply to all biomedical research. Yet the lists are not, nor could they ever be, totally comprehensive. The Council would prefer explicitly stated guiding principles with regard to the information that should be given, followed by considerably shorter lists that would indicate rather than dictate the exact information required. The Council proposes that one such guiding principle should be that research participants should be provided with all the information about the study that may reasonably be thought to affect their willingness to participate.

Article 20 – Protection of persons not able to consent to research; Interventions with minimal risks and minimal burden

The article deals only with risks and burdens in the immediate research situation. There may however be long-term risks associated with the research results rather than with the data collection. Such risk may involve the research participant, his or her family, the community, as well as society at large. We are thinking of for instance the possible impact of retroviruses after xenotransplantation, retrieval of potentially sensitive genetic material, and the keeping of observational recordings. Such possible risks and burdens also need to be taken into account and considered by an ethics committee (see comments on article 11).

Article 21 – Research in emergency clinical situations

It is the opinion of the Council that research in emergency situation should be carried out only if it may be of potential benefit to the person. A clause to this effect should be included in article 21.

Article 23 – Research during pregnancy or breast-feeding

The Council finds it problematic that article 23 presumes that the woman, embryo, foetus and child always share the same status and interests. It may in fact be the case, that a research intervention poses a minimal risk to the foetus, but potential benefit to the woman, or vice versa. Thus, the formulations need to better reflect that the mother and her offspring in some cases may have diverging positions and interests.

It is also he opinion of the Council that that in any research during pregnancy, follow up procedures to evaluate possible effects on the offspring should be considered, and included in the research plan whenever deemed relevant. A clause to this effect should be added to article 23.

Article 24 – Confidentiality and right to information

The obligation to give the participants access to information on their health would, if taken literally, make it virtually impossible to set up a database that is anonymous. This is an accepted procedure in much epidemiological research, and has the virtue of ensuring perfect confidentiality and protection of privacy. It is also not clear what should be considered “health data”. Much research is explorative, the normal biological variations may not be well known, and individual data may therefore not be possible to interpret. It is the opinion of the Council that Article 24 should be less imperative in its formulation.

Article 30 – Safety and supervision: Non-interference with necessary clinical interventions

With regard to placebo treatment, there is a need for a more precise definition of what may be considered "unacceptable risk or burden" than is now provided in the draft protocol or the draft explanatory report. The Council also notes that the draft protocol and the Helsinki Declaration differ in their formulations regarding the use of placebos. In order to provide the third world with affordable treatments for AIDS, it may in some instances be considered acceptable to assign patients to control groups with no assurance of "proven methods of prevention, diagnosis and treatment".

On behalf of the Swedish National Council on Medical Ethics,

Daniel Tarschys
Chairman

Ann-Charlotte Smedler
Council Secretary
Ex officio