THE SWEDISH NATIONAL COUNCIL ON MEDICAL ETHICS
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To the Committee on Bioethics (DH-BIO),
Council of Europe

Comments on a Working document on research on biological materials of human origin from the Committee on Bioethics (DH-BIO), Council of Europe, (DH-BIO/INF (3014) 3)

The Swedish National Council on Medical Ethics (Smer) has been given the opportunity to give comments on a working document on research on biological materials of human origin from the Committee on Bioethics (DH-BIO), Council of Europe.

General comments

Smer welcomes and appreciates that the Committee on Bioethics (DH-BIO) of the Council of Europe updates its recommendations concerning research on biological materials of human origin and by this emphasizes the importance of the ethical considerations concerning these issues at the European level.

It is of great importance to strive for common guidelines for research including materials from biobanks in Europe. Research is taking place in a highly international context with increased exchange and cooperation between research groups across the European countries and from other parts of the world.

Developments in the field of genome sequencing and information technologies highlight the importance of questions concerning privacy and personal integrity raised by research on biological materials even further. An ethical perspective must always be applied to development and research. Every trade-off in favor of research

is not ethically acceptable, and it is not always possible to predict certain outcomes concerning integrity aspects.

In the Swedish debate Smer has repeatedly stressed the importance of integrity and privacy issues concerning large-scale databases/biobanks that contain collections of biological materials without a specific research purpose. For example Smer has proposed that a specific national ethics committee/board should have a monitoring role for this kind of large-scale databases at the national level.[1]

Specific comments

Definition of biological materials

The recommendation lacks a clear definition of biological materials.

Clarification concerning conditions under which a person should be able to/should be allowed to re-examine consent

In article 12 it is important to clarify/state that when consent is given by a written authorization from the representative or an authority, person or body provided for by law, for a person not able to consent, the representative must in their decision have in mind the best interests of the person not able to consent, as a starting point for the decision.

Article 12.4 and article 14.4 states that "Where a person who has not been able to consent, from whom biological materials have been removed for storage for future research attains the capacity to consent, the consent of that person for continued storage and research use of his or hers biological material should be sought." This sentence could preferably be clarified and state that the consent of that person should be sought as soon as possible.

The content of article 12.2 and 14.2 differs to some extent, and can be understood differently. Preferably article 14.2 should be reformulated to better match the writings in article 12.4.

The right to change scope of, or to withdraw, consent or authorization

Article 16 says that a person should retain the right to withdraw or alter the scope of consent, and have the right to have the materials either destroyed or anonymized. It is unclear if it is the person herself who can decide if the materials should be destroyed or anonymized. Further, the limitations concerning anonymization of biological materials should be mentioned, as long as it contains detailed genetic information, it is not possible to guarantee full anonymization of the biological material especially in circumstances under which different databases are linked

[1] Please find opinions from the Swedish Council on Medical Ethics at www.smer.se.

together. It is important that the concept of anonymization is clarified in the document.

In Sweden the prerequisites for withdrawal of consent, are currently under consideration in the revision of the Swedish Act on Biobanks.

Fetal DNA in pregnant women's blood

Another issue related to withdrawal of consent concerns samples containing biological materials from different persons. New research within prenatal diagnosis has shown that blood samples from pregnant women contains biological materials from the fetus. This will enable a complete genome sequencing of the future child, by analyzing a blood sample from the pregnant woman. Biological materials from pregnant women are therefore particularly sensitive from an integrity point of view. This also highlights the question whether the future child also should be informed about previous blood samples and also be given the rights referred to in article 16.

Transborder flows

Article 23 states circumstances under which biological materials should be transferred to another country. Transboarder flows raise questions concerning how to deal with circumstances when countries differs on what they define as biologically identified materials or when the ethical review process differs between the countries. The protection of the individual is not ensured if the application of the law and the ethical review differs. It can be discussed whether the individual has to consent when transferring the biological materials to other countries.

Age categories

The phrase "age category" is used in three places in the document. Age-based categories are particularly problematic when talking about children or the elderly, but there is also another reason: the text is intended to protect individuals, not groups. Group-based reasoning rarely protects individuals. We propose to focus on protecting individuals, and to formulate the text so that it becomes clear that this is the intention.

Recommendation concerning sanctions if the regulation is not followed

The document should also include a recommendation to the member states to enact legislation with sanctions in case the rules are violated.

The Swedish National Council on Medical ethics has discussed the working document during its regular plenary meeting May 23, 2014. This statement has been prepared by professors Göran Hermerén and Nils-Eric Sahlin, both expert members, and professor Kjell Asplund, chair of the Council. Secretary has been Lotta Eriksson, head of the secretariat.

On behalf of the Swedish National Council on Medical Ethics,

Kjell Asplund

Professor, Chair