Bioteknologinemnda
The Norwegian Biotechnology Advisory Board

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Comments from the Norwegian Biotechnology Advisory Board to the draft guidelines on human biobanks and genetic research databases

The Norwegian Biotechnology Advisory Board appreciates the level of detail the draft guidelines provide when suggesting how the principles should be achieved in practice as well as the emphasis the guidelines place on the information to the participants, the possibility to withdraw from the research project and the openness about the research and the results that are obtained. However, it could be emphasised even more clearly in the guidelines that the concern for the participants should be given priority to the interest of the society and the research.

The Board has the following suggestions for additional points the guidelines could address in more detail:

1. Children in genetic research (Principle 4C, Ann. 38)
The draft guidelines do not explore which type of genetic information about children that should be analysed and disclosed to the family of the child, or whether there should be limitations to the kind of analyses that can be done. This could be discussed in the guidelines or in a separate document.

Limitations to the disclosure of genetic predispositions to genetic diseases of a child to the child's family should be explored, attending to the possible risk of psychosocial harm to the child of being seen to be at risk, also taking into account the right of the child not to know, particularly of adult-onset diseases. Also the question of whether the family has a right to get information on the genetic status of their child when the results were not intended for disclosure, should be addressed. Independently, the child could retain its own right to know the results when it is old enough to give a legal consent on its own. Moreover, particular considerations should be given when combining sensitive information about children. Should there be limitations to what the family could consent to here as well?

2. Use of biobanks and databases established for other purposes for research (Scope and Best practice 4.8)
The guidelines should address the particular challenges associated with the use of existing biobanks and databases established for other purposes, like diagnostic, therapeutic, forensic purposes etc. for research. In these challenging field, OECD could contribute by exploring how to solve the problems of getting consent for instance when using diagnostic biobanks for research. Would consent from a

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regional or local ethics committee be enough? Should there be an opportunity to opt out of such research? Would it suffice to make information about the research publicly available and give the participants the opportunity to withdraw from the research? Moreover, the considerations to be addressed when obtaining biological material from autopsies for research purposes should be explored.

Here, we would also like to refer to our comments on the OECD draft guidelines for quality assurance in molecular genetic testing (September 2006). Then, the Advisory Board commented on the grey area between research and quality assurance of molecular genetic testing. Many institutions are running analytical clinical services and researching genetic disorders on the same patients. New knowledge means new genetic tests. The Advisory Board emphasised the importance of being able to draw a line between what is research and what is to be used in a clinical setting and become a part of the patient's journal. Where to draw the line between research and quality assurance in a clinical setting is relevant also to these draft guidelines.

3. The difference between having a disease and being healthy (Ann. 12)
The guidelines would benefit from exploring in more detail the difference between having a disease and being healthy when receiving genetic information, which would be diagnostic or predictive in its nature, respectively. The participants should be well informed in cases where the research will reveal information about individual risk for future diseases so that the participants could decide on whether they want to receive such information. There should also be quality assurance of the risk information before it is disclosed to the participant, and the participant should in such cases be given genetic counselling.

4. Handling of surplus information (Ann. 37)
In many situations, research using new technologies like chip technology, will provide more information than originally sought for. Such surplus information could for instance give information about the risk for particular diseases. How should such surplus information be handled? Should surplus information be disclosed to participants who have asked for feedback on the results of the research?

Yours sincerely

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