



GUIDELINES BY THE SUB-COMMITTEE ON MEDICAL RESEARCH ETHICS:

PATIENT INFORMATION AND CONSENT FORMS RELATED TO DNA SAMPLES TAKEN IN CONNECTION WITH PHARMACEUTICAL RESEARCH

Various tests and treatments for illnesses and exposure to disease of human beings that are based on molecule-genetic knowledge are constantly being developed. For this development work DNA samples are needed from patients and reference persons. International conventions, such as the UNESCO Declaration on the Human Genome and Human Rights and the Council of Europe's Convention on Human Rights and Biomedicine give guidelines for situations in which samples are asked for research aimed at the human genome. The same documents are used as the basis for the statements of the Sub-Committee on Medical Research Ethics regarding the taking of genetic samples.

According to the observations of the Sub-Committee on Medical Research Ethics, collection of DNA samples of research subjects is today included in many clinical studies regarding medicines. It has not always appeared precisely from the research plan what it is intended to study in the samples, and that has not necessarily been known at the stage of collecting the samples.

The Sub-Committee on Medical Research Ethics presupposes that information about at least the following circumstances is included in every research plan related to this theme area as well as in every patient informed consent form.

1 For what purpose is the sample used?

The use of a DNA sample must be clearly defined. For instance: "The sample is used for examining such genetic properties that may be of importance for the study of the kinetics, effects, harmful effects etc. properties of the medicine being examined".

The genetic research aimed at the causes of a disease is ethically more complex. If the samples have not been completely anonymised and they are planned to be used for these purposes, that should be made totally clear to the research subject.

2 What information may the research subject obtain from his/her DNA sample?

The main rule in research of this type is that the results of DNA studies will not be reported to the research subject, since they are difficult to interpret and it is in the light of present knowledge improbable that they would have an impact on the health of the research subject. The research plan must, however, incorporate a plan on how to act if a research subject necessarily wants to know his/her DNA results. Then the

person must be provided an access to genetic counselling, in connection of which he/she can learn these results and be informed about their possible impact. If the DNA samples have been anonymised so that their origin cannot be found out, it naturally is not possible to obtain information on the results.

3 How have problems related to data privacy been solved?

Some research plans start from the assumption that, because of the requirements of data privacy, DNA samples are anonymised so that their origin cannot be traced. This is not, however, possible for instance when information is desired for special reasons about a patient's future health. In this case the samples are often coded so that only the clinical research physician concerned is able to associate the sample with a certain person. Possible anonymising or coding of samples as well as the difference in their meaning have to be explained on the patient informed consent form. It should also be clearly written down in it that the information shall not to be delivered to outsiders.

4 How are the samples stored?

According to the Sub-Committee on Medical Research Ethics it is important that the patient knows where and how long the samples are kept stored and how they are disposed of. This is important because it must be possible for the research subject to interrupt/cancel his/her participation in a study at any stage. In regard to completely anonymised samples interruption/withdrawal is impossible, which must appear from the patient informed consent form.

5 Particular problems related to international multi-centre studies

The DNA samples collected within the framework of international multi-centre research are usually planned to be sent to a certain research centre abroad. The largest pharmaceutical companies would in this way gather "a DNA bank" consisting of the data of persons with different diseases. This has given rise to much debate internationally, and many agencies have concluded that "banks" containing biological samples, their purpose and term should be defined precisely.

Referring to what has been said above the Sub-Committee on Medical Research Ethics recommends that the samples be stored in Finland and sent abroad only for analysis. Furthermore, the Sub-Committee recommends that DNA samples be sent abroad only anonymised or coded.

For the Sub-Committee on Medical Research Ethics

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