SELECTED LEGISLATION AND JURISPRUDENCE

UNESCO

International Declaration on Human Genetic Data

The UNESCO Declaration on Human Genetic Data, published hereafter, sets some non-binding principles for the collection, processing, use and storage of human genetic data, human proteomic data and biological samples (allowing for genetic analysis) (hereafter referred to as collection etc.). Some comments on the text are the following.

Usefulness Declaration: The aim of UNESCO, to set some principles for the protection of human rights worldwide in the fields covered by the Declaration, is, as such, laudable. The main principle to achieve this goal is in article 1.b. (the collection etc. shall be consistent with the international law of human rights). Self-evident the statement may be, its reiteration is notably important for people in countries where the individual human rights profile is low.

Normative weakness: The drafters of the text have carefully avoided to frame the Declaration in terms of rights of individuals (patients), except in relation to the right to decide (not) to be informed about research results (article 10). In the perspective of the aim, this is regrettable.

Moreover, the principles, as such already not uncommon, are worded in general terms, leaving exceptions to domestic law. Given the non-binding nature of the Declaration, one could have expected at least some more clear-cut practical guidance on issues where some normative international assistance is still lacking. An example is the framing of consent in relation to storage and future research use of biological samples and personal data.

There is some inconsistency in the text also. Despite their value as carrier of information, some pertinent principles apparently do not pertain to biological samples (e.g. article 5, purposes of collection, article 7 non- – discrimination/stigmatisation).

Procedures: Ethics committees at national level are given an important say in the development of standards regulations and guidelines for the collection etc. And also in all other issues related to genetic data and samples (article 6b.) In relation to the latter, the ethics committee is given a decision-making position in case of
change of purpose of use of genetic data in situations where prior, free informed and express consent cannot be obtained and the law does not provide for that situation (article 16b). It is noteworthy that in relation to biological samples the procedure is not one of domestic law or else the ethics committee as is the case with genetic data, but is a cumulative one (article 17a). Also noteworthy is that no role is foreseen for public national institutes/officials for data-protection.

**Genetic exceptionalism:** The Declaration affirms in its preamble that genetic information is part of medical data in general, that the impact of the use of informational content of medical (genetic) information is highly contextual and that all medical (genetic) data should be treated with the same high standards of confidentiality. This rejection of “genetic exceptionalism” is however mere lip service because at the same time the special status of the genetic information is emphasised both in the preamble and the core of the text. The specific status given to genetic information is based on a misconception. Specific features genetically related information sometimes may have, they do not yet warrant a specific status. Some of the reasons for the special status cited in article 4 also can apply to other medical data. As for instance testing for contagious diseases may have ramifications for the family; blood donations may also contain information (in relation to blood transmissible diseases) not yet known at the time of collection.

To single out genetic data from medical data is most unfortunate. It gives the false impression that the pertinent individual human rights frame does not apply to other medical data (or for that matter biological samples used for non-genetically related testing or research purposes), e.g. informed consent for collection, the right of the source to have control over his tissue and data, and to have his rights to confidentiality and privacy protected. This is an even weightier question, because in many genetically related research projects personal medical data are used as well. Genetic information has always been there, collected through for instance family history. Whilst certain medical, non-genetic, data are as sensitive as certain genetic data can be (HIV for instance), not all genetic information is more sensitive than the ordinary medical information. Genetic data no doubt are sensitive data, but so are all medical data. It follows from the right to a private sphere that the more risk of intrusion, the more stringent the rules for protection ought to be. The mere quantity of genetic information which may be collected, certainly makes the personal information more vulnerable for misuse and abuse, for discrimination and stigmatisation and difficulties with employment and insurance. But similarities between genetic and non-genetic medical data are such that the genetic information is not qualitatively different. It is not so much the nature of a test itself (involving genetic data or not) but rather the information it produces that determines the degree of sensitivity in relation to the context in which it may be put to use, and the legal issues inherent to it.