



Comments on the World Medical Association Declaration on Ethical Considerations Regarding Health Databases and Biobanks

by

the TMF biobanking working group

in co-operation with

**the Network of Coordinating Centres for Clinical Trials
(KKS-Network)**

The TMF-biobanking working group and KKS-Network thank the World Medical Association for the invitation to submit some comments on the Declaration on Ethical Considerations Regarding Health Databases and Biobanks for further consideration.

1. Anonymization

Anonymization is problematic for several reasons and should not be recommended anymore as a privileged method to protect confidentiality and privacy:

First, it weakens the usefulness of data analysis and interpretations to produce high quality research, since any loss of information due to the anonymization procedure leads inevitably to deficits in obtaining comprehensive scientific results.

Secondly and even more important, anonymization does not strengthen, but to the contrary weakens the rights of the donors, since they lose their right to withdraw their consent. This is not at all compensated by the effect of anonymization, since effectively anonymizing biosamples and/or genetic data, which is rich enough not to single out a person, belongs to the past. The Art 29 Working Party under the EU Data Protection Directive has stated in its Opinion on Anonymization Techniques (p.10): "Genetic data profiles are an example of personal data that can be at risk of identification if the sole technique used is the removal of the identity of the donor due to the unique nature of certain profiles. It has already been shown in the literature that the combination of publically available genetic resources (e.g. genealogy registers, obituary, results of search engine queries) and the metadata about DNA donors (time of donation, age, place of residence) can reveal the identity of certain individuals even if that DNA was donated 'anonymously'.". Indeed, re-identification techniques are





constantly progressing. The field needs further debate. But it is quite clear, that anonymization of such data cannot be recommended any more as general means to protect donor's privacy without a feeling to betray donors. Next generation sequencing makes it more and more affordable and achievable to extract data from biosamples.

Thirdly the donors / patients cannot be contacted any more in case of incidental findings. Beyond the ethical issues around feeding back incidental findings, it cannot be seen as solution to anonymize and thus exclude any feedback. Especially in cases of changes in oncological treatment protocols, which need readily to be returned for the benefit of the donors / patients (well-being), pseudonymization is highly preferable and can already be seen as prevailing practice.

2. Definitions of terms

For the sake of clarity we further recommend to introduce a definition section / supplement where terms need to be addressed: pseudonymized (point 8); health database (point 2); ...other purposes (point 2); biological material; blanket vs. open vs. broad vs. conditional broad consent (point 18); genetic information (point 7).

3. Biobanking is an interdisciplinary field in biomedical research

Biobanking has become an interdisciplinary scientific effort meanwhile. Thus, not only physicians, but also researchers from diverse disciplines and institutions (e. g. Informatics, Statistics, Molecular Biology / Genetics, Epidemiology, Psychology, Public Health etc.) can be appropriately qualified for the governance, responsibility of biobanks, and can also safeguard privacy issues (see Governance point 23 to 26ff), as well as they are obliged to confidentiality (see point 14).

Furthermore, we would recommend that point 23 should be followed by the details in point 26. Because of the interdisciplinary character, governance rules will most probably be formulated by relevant authorities (see point 27). We would therefore suggest changing the word "must" in points 23 and 26 to "should".

4. General Remark

The text is focusing on Health Databases and Biobanks in general. Because of the mandate of the WMA, we would recommend to add a statement similar to paragraph 2 of the preamble of the Declaration of Helsinki.