THE WORLD MEDICAL ASSOCIATION, INC.
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December 20th, 2016

LETTER OF THANKS

WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks

Dear Colleagues, Researchers, Friends of the WMA,

The WMA General Assembly adopted the new Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks at its General Assembly last October. This was the first tangible result of a four year process that started parallel to the adoption of the 2013 (Fortaleza) version of the Declaration of Helsinki (DoH) and the request that the WMA find a better solution to protect the rights of individuals when donating data or human material.

You have – in one way or another – participated in the development of this policy. You have advised us or offered constructive criticism, you have shared experiences and insights, have highlighted limitations and options. We are most grateful for this input and believe it has made our approach and the final document very comprehensive and strong yet pragmatic.

Starting with the DoH, which gives some guidance on the secondary use of data, we knew from the outset that this was not sufficient because collections of data and materials are increasingly intended for multiple use. Later, we also came to realise that focusing on research was no longer realistic as the commercial value of health data has long been recognised.

Achieving our aims to sustain the level of protection that can ideally be achieved with informed consent, on the one hand, and to find a practical and widely applicable solution for facilitating research with databases and biobanks on the other seemed to be like squaring the circle. It was clear that we could not give up the protection level of informed consent by simply applying "general" or "broad" consent while the key information for informed consent was not (yet) available, future research maybe not even having been conceptualised at the moment when data or materials are collected. But it was equally clear that repeatedly asking donors of data or material for consent, potentially several times a year, would not work either.

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We also found early on that the ethical challenges of setting up, managing and using databases and biobanks may not be identical, but are very similar and often overlapping. The arguments we heard did not convince us to separate these issues, rather the interchangeability of tissue (especially genetic material) and data was a compelling argument to deal with them together.

Several contributors asked us to limit the policy to research use only. In the political discussion about data protection an idea was put forward to have fewer restrictions for research than for other use. There is also a notion that research use is, seen at first glance, more ethical than commercial or administrative use; a notion that we did not find to be automatically warranted.
However, it has been our tradition that we as physicians have nearly always applied higher and much stricter standards than other users of medical data. This has not hindered research, it builds trust and helps researchers to better understand the importance of good relationships with individuals and their communities.

In the end, we neither found it practical nor justifiable to have different ethical principles for different uses, especially understanding that conducting research is one of the civil freedoms (even marketing can easily be camouflaged as research) in most of the societies of this world, and that the definition of what research is is by no means clear enough.

The work group preparing the policy was also confronted with the question of whether research with data and/or human materials gained without any invasive methods or other stresses justifies a detailed process, as risks and burdens may be minimal or non-existent. Indeed, we expect that most uses of data may produce no or nearly no risks or burdens; however these cannot be generally excluded. There may be findings that produce knowledge about a disease resulting in the loss or exclusion from insurance coverage, or which may point to an untreatable disease, or may lead to stigma if known of by others. Health data can and has been abused for political purposes and it can – at least theoretically – be used to secretly ration care or engage in cherry picking. As much as we trust in the opportunities of using health data on a large scale, we are aware of the potential for abuse. Finally, new IT methods for using what is generally known as “big data”, frequently using information from millions of individuals, will increase the quantity of scenarios for potential misuse or abuse. This large quantitative change in the use of health data itself generates a new quality of risks and dangers.

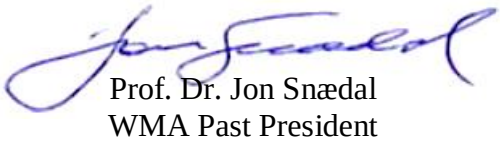
The Declaration of Taipei offers a three-step procedure to safeguard autonomy, privacy and the dignity of the person donating data and/or material. In brief:

1. There has to be a clear, ethically acceptable reason to start and maintain a database.
2. When collecting data or material, the donor shall give consent on the basis of a clearly defined set of information. As the ramifications, risks and burdens that a potential use may entail are not clear at this point, the information will concentrate on explaining how a governance process will ensure the protection of the person’s rights.
3. A governance process by which an ethics committee review will determine which type of consent is necessary for each intended use of the database or biobank. Initial consent may be sufficient because a risk or burden for the donor (or his/her relatives) can be excluded. Or it may be necessary to put safeguards in place (e.g. anonymization, pseudonomization or coding, and/or aggregation of data), or the committee may find risks and burdens foreseeable and determine that the individual donor has to be asked for full-fledged informed consent.

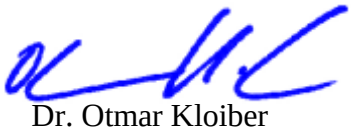
The WMA is well aware that with the current data sharing behaviour of many people, data collection by wearable sensors and their connectedness, the majority of health data will be generated and exchanged without the participation of physicians, the only group we can speak for. However, we are hopeful that this policy will inspire politicians and data protection officers to engage in better protection of health data, as we all know is required.

Thank you for supporting us in this important task. The development of research and the use of big health data are still in their infancy and we all are just learning as we go along. We are sure that this was only the beginning of the journey, and that we will return to this subject on many future occasions.

Sincerely,



Prof. Dr. Jon Snædal
WMA Past President
Chair of the Database Work Group



Dr. Otmar Kloiber
Secretary General