



WMA DECLARATION OF TAIPEI ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS

*Adopted by the 53rd WMA General Assembly, Washington, DC, USA,
October 2002
and revised by the 67th WMA General Assembly, Taipei, Taiwan,
October 2016*

PREAMBLE

1. The Declaration of Helsinki lays down ethical principles for medical research involving human subjects, including the importance of protecting the dignity, autonomy, privacy and confidentiality of research subjects, and obtaining informed consent for using identifiable human biological material and data.
2. In health care provision, health information is gathered by physicians or other members of the medical team to record health care events and to aid physicians in the on-going care of their patient.
3. This Declaration is intended to cover the collection, storage and use of identifiable data and biological material beyond the individual care of patients. In concordance with the Declaration of Helsinki, it provides additional ethical principles for their use in Health Databases and Biobanks.

This Declaration should be read as a whole and each of its constituent paragraphs should be applied with consideration of [Back to Top](#) other relevant paragraphs.



5. Research using Health Databases and Biobanks can often significantly accelerate the improvement in the understanding of health, diseases, and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions. Health research represents a common good that is in the interest of individual patients, as well as the population and the society.

6. Physicians must consider the ethical, legal and regulatory norms and standards for Health Database and Biobanks in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for individuals and population set forth in this Declaration.

When authorized by a national law adopted through a democratic process in respect of human rights, other procedures could be adopted to protect the dignity, autonomy and privacy of the individuals. Such procedures are only acceptable when strict rules on data protection are implemented.

7. Consistent with the mandate of WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in using data or biological material in Health Databases and Biobanks to adopt these principles.

ETHICAL PRINCIPLES

8. Research and other Health Databases and Biobanks related activities should contribute to the benefit of society, in particular public health objectives.

9. Respecting the dignity, autonomy, privacy and confidentiality of individuals, physicians have specific obligations, both ethical and legal, as stewards protecting information provided by their patients. The rights to autonomy, privacy and confidentiality also entitle individuals to exercise control over the use of their personal data and biological material.

10. Confidentiality is essential for maintaining trust and integrity in Health Databases and Biobanks. Knowing that their privacy will be respected gives patients and donors the confidence to share

[Back to Top](#)



sensitive personal data. Their privacy is protected by the duty of confidentiality of all who are involved in handling data and biological material.

11. The collection, storage and use of data and biological material from individuals capable of giving consent must be voluntary. If the data and biological material are collected for a given research project, the specific, free and informed consent of the participants must be obtained in accordance with the Declaration of Helsinki.

12. If the data or biological material are collected and stored in a Health Database or a Biobank for multiple and indefinite uses, consent is only valid if the concerned individuals have been adequately informed about:

- The purpose of the Health Database or Biobank;
- The risks and burdens associated with collection, storage and use of data and material;
- The nature of the data or material to be collected;
- The procedures for return of results including incidental findings;
- The rules of access to the Health Database or Biobank;
- How privacy is protected;
- The governance arrangements as stipulated in paragraph 21;
- That in case the data and material are made non-identifiable the individual may not be able to know what is done with their data/material and that they will not have the option of withdrawing their consent;
- Their fundamental rights and safeguards established in this Declaration; and
- When applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data or material to other institutions or third countries.

13. In addition to the requirements set forth in the Declaration of Helsinki, when persons who were not able to consent, whose data and biological materials have been stored for future research, attain or regain the capacity to consent, reasonable efforts should be made to seek the consent of those persons for continued storage and research use of their data and biological materials.

[Back to Top](#)



15. Individuals have the right, at any time and without reprisal, to alter their consent or to ask for their identifiable data to be withdrawn from the Health Database and their biological material to be withdrawn from a Biobank. This applies to future use of the data and biological materials.

16. In the event of a clearly identified, serious and immediate threat where anonymous data will not suffice, the requirements for consent may be waived to protect the health of the population. An independent ethics committee should confirm that each exceptional case is justifiable.

17. The interests and rights of the communities concerned, in particular when vulnerable, must be protected, especially in terms of benefit sharing.

18. Special considerations should be given to the possible exploitation of intellectual property. Protections for ownership of materials, rights and privileges must be considered and contractually defined before collecting and sharing the material. Intellectual property issues should be addressed in a policy, which covers the rights of all stakeholders and communicated in a transparent manner.

19. An independent ethics committee must approve the establishment of Health Databases and Biobanks used for research and other purposes. In addition the ethics committee must approve use of data and biological material and check whether the consent given at the time of collection is sufficient for the planned use or if other measures have to be taken to protect the donor. The committee must have the right to monitor on-going activities. Other ethical review mechanisms that are in accordance to par 6 can be established.

GOVERNANCE

20. In order to foster trustworthiness, Health Databases and Biobanks must be governed by internal and external mechanisms based on the following principles:

[Back to Top](#)



- Transparency: any relevant information on Health Databases and Biobanks must be made available to the public;
- Participation and inclusion: Custodians of Health Databases and Biobanks must consult and engage with individuals and their communities.
- Accountability: Custodians of Health Databases and Biobanks must be accessible and responsive to all stakeholders.

21. Governance arrangements must include the following elements:

- The purpose of the Health Database or Biobank;
- The nature of health data and biological material that will be contained in the Health Database or Biobank;
- Arrangements for the length of time for which the data or material will be stored;
- Arrangements for regulations of the disposal and destruction of data or material;
- Arrangement for how the data and material will be documented and traceable in accordance with the consent of the concerned persons;
- Arrangement for how the data and material will be dealt with in the event of change of ownership or closure;
- Arrangement for obtaining appropriate consent or other legal basis for data or material collection;
- Arrangements for protecting dignity, autonomy, privacy and preventing discrimination;
- Criteria and procedures concerning the access to and the sharing of the health data or biological material including the systematic use of Material Transfer Agreement (MTA) when necessary;
- The person or persons who are responsible for the governance;
- The security measures to prevent unauthorized access or inappropriate sharing;
- The procedures for re-contacting participants where relevant;
- The procedures for receiving and addressing enquiries and complaints.

[Back to Top](#)

22. Those professionals contributing to or working with Health Databases and Biobanks must comply with the appropriate governance arrangements.



24. The WMA urges relevant authorities to formulate policies and law that protect health data and biological material on the basis of the principles set forth in this document.

[Back to Top](#)

