WMA DECLARATION ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS

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A draft from the Work Group intended for open consultation after acceptance of the Executive Committee of the WMA

PREAMBLE

1. The Declaration of Helsinki lays down ethical principles for medical research involving human subjects, including the importance of protecting the privacy and confidentiality of research subjects, and obtaining informed consent for using their health data and biological material.

2. This declaration provides additional principles for the ethical use of data in Health Databases and human biological material in Biobanks, referred to hereafter as biological material, used for research or for other purposes.

3. A Health Database is a system for collecting, organizing and storing health information. It enables the information to subsequently be retrieved in a structured manner. A Biobank is a collection of biological material and associated data from different individuals. Health Databases and Biobanks are both collections of information on individuals, and both give rise to the same concerns about autonomy, privacy and confidentiality

4. 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. This declaration is intended to cover any use of health information beyond the individual care of patients.

5. Respecting the dignity and autonomy of individuals, physicians have specific obligations, both ethical and legal, as stewards protecting information provided by their patients

6. Ongoing improvements in the understanding of diseases and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions can be significantly accelerated through research using data from Health Databases and Biobanks.

7. Biological material refers to a sample obtained from an individual human being, living or deceased, which can provide biological information, including genetic information, about that individual.

8. Health Databases and Biobanks that exclusively contain fully anonymised and non-identifiable data and biological material are not the subject of this declaration.

9. Anonymous or pseudo anonymous data are always preferable to identifiable data, whenever satisfactory for the purpose of a Health Database.

10. Physicians, administrators, medical researchers and health policy makers must observe the provisions outlined in this Declaration.

ETHICAL PRINCIPLES

13. The right to privacy, confidentiality and self-determination entitles people to exercise control over the use of and disclosure of information about them as individuals.

14. Confidentiality is essential for maintaining trust and integrity in the patient-physician relationship. Knowing that their privacy will be respected gives patients the confidence to share sensitive personal information with their physician. The privacy of a patient's information is secured by the physician's duty of confidentiality.

15. Individuals must be given the opportunity to decide whether their identifiable information will, or will not be included in a Health Database or their biological material in a Biobank. As part of the consent process, individuals must be informed about the purpose of the Health Database or Biobank, the nature of the data or material to be collected and about who will have access to the Health Database or Biobank. They must also be informed about the governance arrangements and the means that will be used to protect the privacy of their information.

16. Individuals have the right to solicit and be provided with information about their data and its use as well as to request necessary corrections of mistakes or omissions.

17. Individuals must have the right to, at any time and without reprisal, withdraw their consent for their identifiable information to remain included in a Health Database and their biological material to remain in a Biobank.

18. If Health Databases and Biobanks are established to allow for multiple studies and if, during the consent process, all principle information about future use is provided, all relevant safeguards are secured, the use of health data or biological material is transparent, and if all use is explicitly approved by a dedicated, independent ethics committee, then conditional broad consent is acceptable. In contrast, blanket or open consent for future use of health data or biological material not envisaged at the time of collection is not ethically acceptable."

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

20. A dedicated independent ethics committee must approve the establishment of Health Databases and Biobanks used for research and other purposes.

21. The ethics committee must approve all use of data and human material and decide on the type of consent necessary, taking into consideration risks and benefits of the activity. The committee must have the right to monitor ongoing activities.

22. Special considerations should be given to the possible exploitation of intellectual property. Protections for ownership of materials, rights and privileges must be considered before collecting and sharing the material.

GOVERNANCE

23. Health Databases and Biobanks must be appropriately managed and safeguarded.

24. Those health professionals contributing to or working with Health Databases and Biobanks must ensure they make themselves aware of appropriate governance arrangements.

25. An appropriately qualified physician should be appointed to safeguard Health Databases or Biobanks with responsibility for ensuring compliance with this declaration.

26. Governance arrangements must include:

26.1 The purpose of the Health Database or Biobank;
26.2 The health data and biological material that will be contained in the Health Databases or Biobank;
26.3 Arrangements for the length of time for which the data or material will be stored;
26.4 Arrangement for obtaining appropriate consent or other legal basis for data collection;
26.5 Arrangements for protecting privacy, confidentiality and autonomy;
26.6 How the health data or human material will be accessed;
26.7 The person or persons who are responsible for the governance;
26.8 The procedures for receiving and addressing enquiries and complaints;
26.9 The security measures to prevent inappropriate or unauthorized access;

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