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Supporting Responsible Samples and Data Sharing When Regulation comes into play: The World Medical Association Declaration of Taipei

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A new regulatory tool

The Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks has been adopted by the 67th WMA General Assembly, Taipei, Taiwan, **October 2016**

Revision of the 53rd WMA General Assembly Declaration, Washington, DC, USA, October 2002

Rationale of this new Declaration

- **The World Medical Association's (WMA) Declaration of Helsinki of 1964 (revised in 2013) –** general guidelines for medical research on human beings
- **The research has been evolving** since the Declaration of Helsinki and the research infrastructures too
- **Large collections of data and human samples** allow for the development of new research strategies and models, as well as new predictive types of research and analysis.
- **The potential of biobanks and health databases is vast, but so are the potential dangers** as regard to human rights
- Need to address the **specific needs** of these infrastructures in terms of ethical management

WMA repositories' definitions

- A "**Health Database"** is a system for collecting, organizing and storing health information.
- **A "Biobank"** is a collection of biological material and associated data. 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.
- **"Health Databases" and "Biobanks"** are both collections on individuals and population, and both give rise to the **similar concerns** about individuals' rights and freedoms protection.

Objectives

- **Provide additional ethical principles to the Declaration of Helsinki for their use in Health Databases and Biobanks.**
- **Achieve a balance** between the rights of individuals giving their tissue or data for research and other purposes, based on confidentiality and privacy rules
- **Adopt an international (global) policy** to address **any use** of health databases and biobanks **excluding individual treatment** and **not restricted to research** (in contrast to the Declaration of Helsinki)

Scope

- **Address primarily to physicians** but also **biobank/database managers**; any custodian of samples/data
- Covers the **collection, storage and use of identifiable data and biological material (any kind of samples)** beyond the individual care of patients.
- Provide **guidance for future research uses** of samples and data
- Provide **guidance on governance** mechanisms

Content

- Ethical principles
  - Research and other Health Databases and Biobanks related activities shall **contribute to the benefit of society, in particular public health objectives.**
  - Physicians have specific obligations, both ethical and legal, as stewards protecting information provided by their patients: protect the **dignity, autonomy, privacy and confidentiality of individuals**
  - Individuals enjoying rights to autonomy, privacy and confidentiality are entitled to exercise **control over the use of their personal data and biological material.**

- **Privacy at the heart of the trusty relationship in research** between individuals (research participants) and the physicians and other professionals involved in biobanking and databases management, for ensuring confidence to share sensitive personal data.
- **Informed consent prior to the collection, storage, use**
  - ✓ Ensure voluntary participation
  - ✓ Information must be adapted to the purposes and adequately communicated to the individuals
  - ✓ **For a given project:** specific informed consent
  - ✓ **For multiple and indefinite uses:** broad informed consent

- **Broad informed consent recognition**
- **Special validity conditions relying: participants shall be informed about:**
  - ✓ The **purpose(s)** of the Health Database or Biobank;
  - ✓ The **risks and burdens** associated with collection, storage and use of data/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** protection measures;
  - ✓ The **governance arrangements** in place;
  - ✓ **Consequences of anonymization** on data/samples participant's control;
  - ✓ Their **fundamental rights and safeguards established in the Declaration**; and
  - ✓ **When applicable,** commercial use and benefit sharing, intellectual property issues and the transfer of data or material to other institutions or 3rd countries.

- Regarding future uses of the samples/data
  - **Individual right to alter their consent**
  - **Individual right to withdraw from the Health Database and from a Biobank.**
    - ✓ Ask for the erasure of identifiers (anonymization)
    - ✓ Ask for the destruction of the data /material

- **Special safeguards for vulnerable persons and populations** as stated in the Helsinki Declaration, **plus special considerations should be taken as regard to benefit sharing policy**
- An **independent ethics committee (by law/internal)** must approve:
  - The establishment of Health Databases and Biobanks used for research and other purposes
  - The use of data and biological material
  - The sufficiency of the given consent at the time of collection for the planned use(s).
- **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 principles
  - **Priority to the protection of individuals**
  - **Transparency**
  - **Participation and inclusion**
  - **Accountability**

Governance arrangements must describe among others:

- **Informed consent processes** or other legal basis for data or material collection;
- **Storage duration** of samples/data;
- **Regulations of the disposal and destruction** of samples/data;
- **Documentation and traceability** of the samples/data in accordance with the consent of the concerned persons;
- **Security measures** to prevent unauthorized access or inappropriate sharing;
- How the samples/data will be dealt with in the case of **change of ownership or closure**;
- **Access criteria and procedures** including the systematic use of Material Transfer Agreement (MTA) when necessary;
- **Person(s) who are responsible** for the governance;
- **Procedures for re-contacting participants** where relevant;
- **Procedures for receiving and addressing enquiries and complaints.**

CONCLUSION

- New specific regulatory tool for supporting sustainable international research based on samples/data sharing
- Structural guidelines for repositories (individually/for networks)
- An innovative approach standardising governance mechanism for samples and data together with adapted individual rights (e.g. broad consent)
- A complement to the existing Declaration of Helsinki (as well as Council of Europe Recommendations)
- Privacy protection at the center (e.g. EU GDPR…)
- **Use it !**

Thank you for your attention!

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