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

Gauthier Chassang, Emmanuelle Rial-Sebbag
Inserm, UMR1027/US13, BIOBANQUES, France
BBMRI-ERIC CS ELSI – IO Policy Task Force

Global Biobank Week
Stockholm, Sweden
13 Sept. 2017

www.bbmri-eric.eu
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
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!

E-mail: gauthier.chassang@bbmri-eric.eu
gauthier.chassang@inserm.fr

Web: www.bbmri-eric.eu
@BBMRIERIC
BBMRI-ERIC

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 676550.