Original Poster:

XX International Conference on Pharmaceutical Medicine (ICPM), 2020, Rome

Prepared for ICPM 2020, but it was postponed then published in this IFAPP Today No. 19, Dec 2021

A proposal for revision of the Declaration of Helsinki

to promote data-driven science and strengthening human subject protection

Chieko Kurihara, Varvara Baroutsou, Sander Becker, Johan Brun, Brigitte Franke-Bray, Roberto Carlesi, Anthony Chan, Luis Collia, Sandor Kerpel-Fronius, Peter Kleist, Luís Filipe Laranjeira, Kotone Matsuyama, Shehla Naseem, Johanna Schenk, Honorio Silva

Ethics Working Group of the International Federation of Pharmaceutical Physicians and Pharmaceutical Medicine

https://ifapp.org/working-groups/ethics-and-professionalism

Search: IFAPP ethics

Background:

- The Declaration of Helsinki (DoH) was revised in 2013 and the Declaration of Taipei (DoT) was adopted in 2016 by the World Medical Association (WMA).
- DoH is for research involving human subjects including individual identifiable data or material.
- DoT is for health databases and biobanks, developed in response to expansion of data-driven research in 21st century.
- However, ethical principles for secondary use of data/material obtained in research remain unclear.

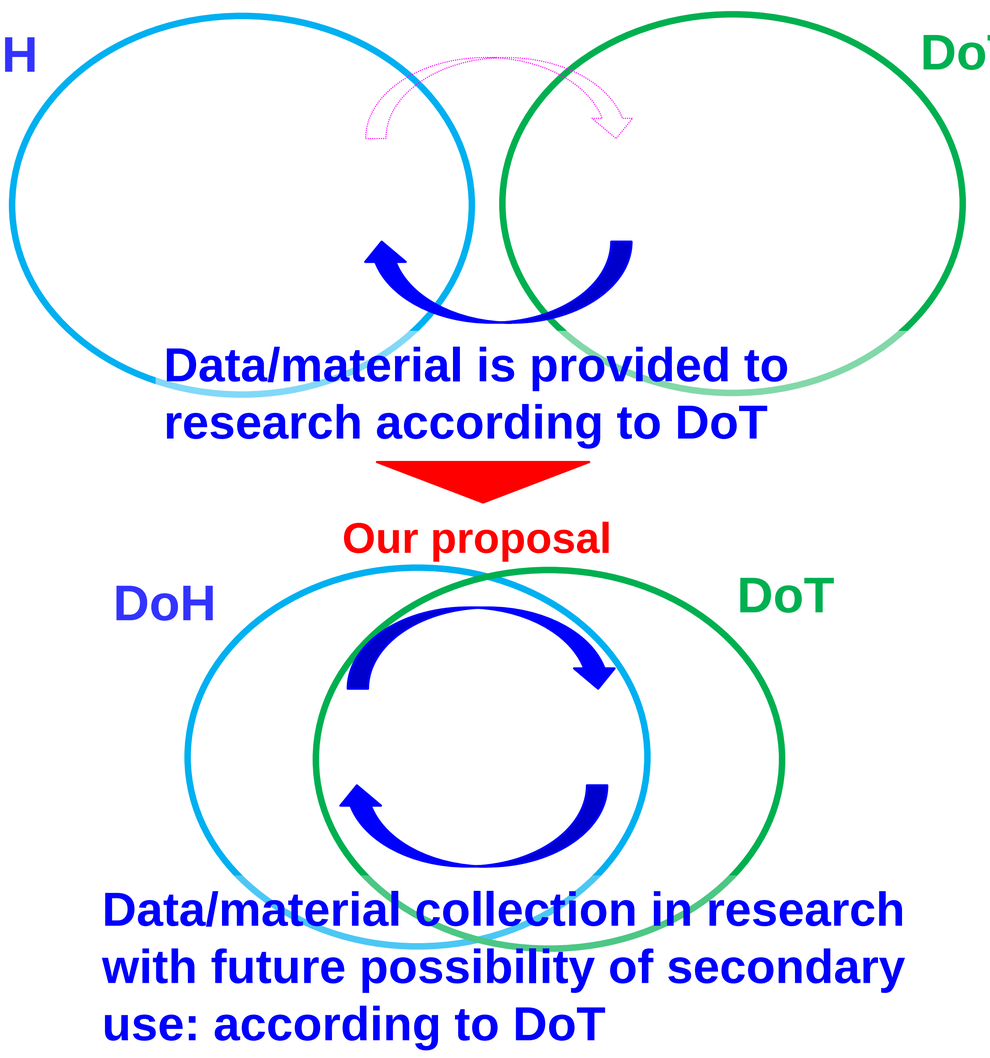
Objectives:

- IFAPP's recommendation for DoH on its necessary revisions to promote data-driven research, while continuing to strengthen human subject protection.
- This recommendation is based on official request from the WMA under the MoU for mutual cooperation.

Recommendations:

1. Connection between DoH and DoT

Data and/or biological material collected as a part of the research, which may be used for secondary analysis, should be in the scope of DoT, and this should be clarified in the "**General Principles**" of the DoH.



2. Ethical approval and consent for secondary use

- If the data/samples collected in research is anticipated to be used for other purposes after the research (="secondary use"), it should be included in the research protocol for ethical approval.
- Informed consent should be obtained separately.
- This should be clarified by revisions of **paragraphs 22 (protocol) and 26 (informed consent).**

Protocol title
Informed Consent Form

Participation in clinical trial

Signature **Date**

Secondary use of Data/Sample

Signature **Date**

3. Incidental findings

- The right of an individual of taking option of knowing/not knowing the research results should be assured.
- "Incidental findings" (IFs) during the research should follow the same principle, which should be clarified in **paragraph 26**. Examples:

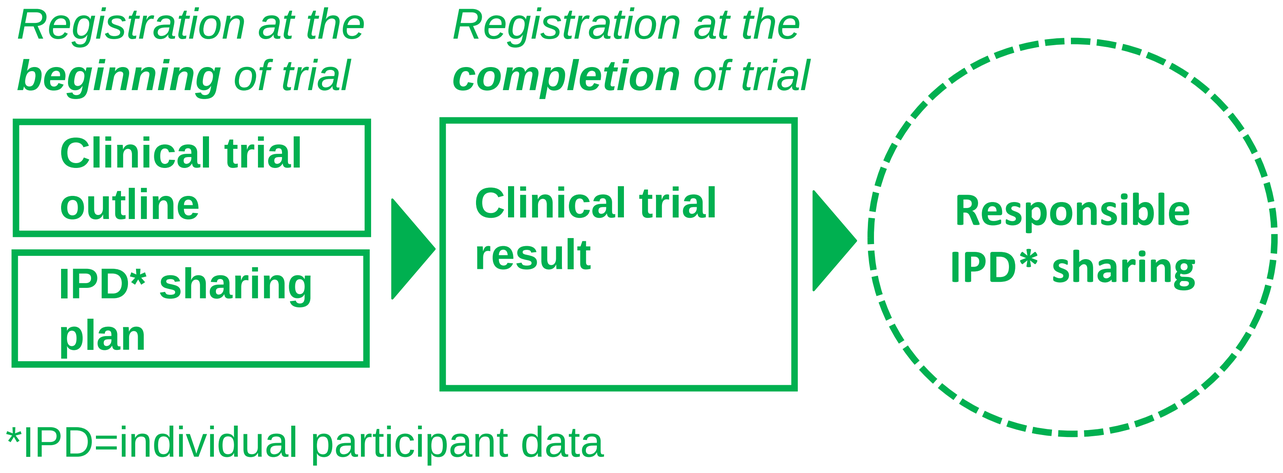
◆Imaging of brain of healthy volunteer in AD* drug study.
◆IF of brain tumor.

*AD=Alzheimer disease

◆Pharmacogenetics clinical trial.
◆IF of unproven genetic factor.

4. Sharing of study results and individual data

- In addition to registration of study outlines in public databases, registration of "data sharing plan" and "result" should be added to **paragraph 35**.



*IPD=individual participant data