A Code of Conduct for Health and Life science in Europe

Professor Jan-Eric Litton

2017-11-08
Big data - driven Health?

Personalized Medicine a key driver for Exascale ICT from Intel 2012
BBMRI-ERIC - largest infrastructure for health in Europe

**Members**
- Austria
- Belgium
- Czech Republic
- Estonia
- Finland
- France
- Germany
- Greece
- Ireland
- Italy
- Latvia
- Malta
- Netherlands
- Norway
- Poland
- Sweden
- United Kingdom

**Observers**
- Cyprus
- Switzerland
- Turkey
- IARC
Directory 3.2

100M samples
Tools
Connector
BBMRI-ERIC Directory

RD Connect

makes your Registry/Biobank visible

PROPOSE - Registry/Biobank
BROWSE - The RD Connect Network
What happens to the data of a rare disease patient?

Where does my data go? Who can access my data? Is my data safe? Will my data be useful?
RD-Connect’s guiding principle

Overcoming silos

Data sharing for research and better data analysis
Enabling data linkage and reuse

Biomarker study

Biobank

Registry

Clinical trial

Natural history

Registry

Biomarker study
Concern: Health research is not specifically addressed

(a) Conditions for consent
(b) Secondary use of data
(c) Personal data versus anonymised data
(d) Defining and dealing with genetic data
(e) Data/sample transfer to 3rd countries and international organisations
(f) EOSC

• Interpretation and implementation of the EU data protection framework could differ considerably
Recitals and Articles in the GDPR which provide some latitude to Member States to shape the GDPR in relation to research

- Recitals 33, 34, 53, 159, 161
- Articles 1, 4, 5, 6, 9, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 32, 34, 89
- Interpretation and implementation of the EU data protection framework could differ considerably
Recitals and Articles in the GDPR which provide some latitude to Member States to shape the GDPR in relation to research

- Recitals 33,34,53,159,161
- Articles 1,4,5,6,9,13,14,15,16,17,18,19,20,21,22,32,34,89

- Early signs are of considerable diversity in national implementation
We must urgently clarify data-sharing rules

Scientists have worked hard to ensure that Europe’s new data laws do not harm science, but one last push is needed, says Jan-Eric Litton.

24 January 2017
Before the Summer 2017

1. Identify experts representing a certain range of organisations that can commit to the writing process:
   - Represented organisations are expected to cover their experts’ travel & time in-kind

2. Determine sub-groups based on suggested topics and available experts
   - For drafting sections of the code to be presented and discussed
   - Keep log-book (explanatory memorandum) - throughout
After The Summer 2017-2018

3. Present and discuss results from sub-groups
   - Suggested format: online and/or in person discussions with stakeholders
   - Incorporate feedback – autumn 2017

4. DPA consultation Dec 2017 – Jan 2018

5. Prepare draft of the whole document and ensure public consultation - 1 March 2018

6. Code of Conduct proposal to be submitted to the EC (process yet to be defined) plus high level seminar – 25 May 2018
Why Anonymous Data sometime isn’t

Each time you use a digital device and, for example, surf the Internet, use your mobile and visit websites, your activities leave small marks behind them.
Why Anonymous Data sometime isn’t

INTERNET OF THINGS SOLUTIONS FOR HEALTHCARE
NURBS 1986
NURBS 1986
NURBS 2017

iPhone X
Say hello to the future.
Why Anonymous Data sometime isn’t

No matter how high the data protection standards are set, there will always remain some risk of (re-)identification of individuals and disclosure of sensitive information about them.

What is needed is the tightening of rules to protect against privacy violation in health and life science...

.. such as discrimination based on genetic information like U.S. Genetic Information Non-discrimination Act (GINA) is a good starting pont
Why Anonymous Data sometime isn’t

Given the use of human material and data in medical research, we might need privacy-protecting principles related to compliance with data protection regulations.
Concern: Health research is not specifically addressed

- Conditions for consent
- Secondary use of data
- Personal data versus anonymised data
- Defining and dealing with genetic data
- Data/sample transfer to 3rd countries and international organisations
- EOSC

Interpretation and implementation of the EU data protection framework could differ considerably
Article 40: Associations and other bodies representing categories of controllers or processors may prepare codes of conduct
Aim if the Code of Conduct for Health Research

- To develop a sector specific code that explains how the GDPR applies in practice in health research;
- To contribute to the proper application of the regulation, taking into account the specific features of processing personal data in the area of health;
- The code has to be comprehensive to non-legal experts;
- To clarify and specify certain rules of the GDPR for controllers who process personal data for purposes of scientific research in the area of health;
- To help demonstrate compliance by controllers and processors with the regulation;
- To help foster transparency and trust in the use of personal data in the area of health research.
Code of Conduct - Governance

FORUM

Reference Group 1
Reference Group 2
Reference Group 3
Reference Group 4
Reference Group 5

Drafting Group

Public Consultation
Reasons a Code of Conduct

Consistency: Health Data is a complex multiple source/multiple user environment

- Provider reassurance
- Support public/private collaboration
- External accountability to patients/citizens can be enhanced

The Commission has indicated the importance of the “representativeness” of codes

Sectoral Code

- can respond to sectoral specificities
- Offer solutions to Member States
The road to a: 
Code of Conduct for Health Research
Governance of the Code

*Code is a living document!*

- Defining governing bodies
- Defining monitoring mechanisms
Governance of the Code

*Code is a living document!*
- Defining governing bodies
- Defining monitoring mechanisms

http://code-of-conduct-for-health-research.eu/
A Code of Conduct for Health Research

Why do we need a Code of Conduct for Health Research?

The EU General Data Protection Regulation comes into force on 25 May 2018, with direct effect in Member States. Given that legal texts are not always easily accessible, a Code of Conduct for Health Research is being developed that is as comprehensive as possible in order to:

- guide researchers and administrative staff;
- reduce unnecessary fear relating to compliance; and
- enhance data sharing for the purpose of stimulating progress in research.
Thank you!

jan-eric.litton@bbmri-eric.eu

http://code-of-conduct-for-health-research.eu