



**BBMRI-ERIC**

Biobanking and  
BioMolecular resources  
Research Infrastructure

# Towards Code of Conduct on Processing of Personal Data for Purposes of Scientific Research in the Area of Health

19/4/2017

[www.bbmri-eric.eu](http://www.bbmri-eric.eu)



# WHAT HAPPENED SO FAR?

# 2015-2016

- Holding a Day of Action on the draft EU GDPR in Brussels
- Issuing a Position Paper on the draft EU GDPR
- Engaging with multiple stakeholders continuously (e.g., EU, patient advocacy) on GDPR and interest in Code of Conduct
- Publishing FAQs on the EU GDPR (V2.0)
- Collaborating with other BMS Research Infrastructures on Code of Conduct (CORBEL project)



**2017 – taking up speed**

# 24 January 2017

## Nature article

nature

International weekly journal of science

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NATURE | COLUMN: WORLD VIEW



BBMRI-ERIC

## 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

# 1 February 2017

## First Working Meeting

### BBMRI-ERIC WORKING MEETING: THE ROAD TO A HEALTH & LIFE SCIENCES GDPR CODE OF CONDUCT

1 FEBRUARY 2017, BRUSSELS, RUE DE LA SCIENCE 14B

Time	Draft agenda
14:00	<b>Why do we need a Code of Conduct? What is at Stake?</b> Prof Jan-Eric Litton, Director General of BBMRI-ERIC
14:10	<b>The Experience in Developing IMI Code of Practice</b> Irene Schlünder (BBMRI-ERIC)
14:20	<b>An Industry Perspective</b> Brendan Barnes (EFPIA)
14:30	<b>An International Perspective</b> Jasper Bovenberg (BBMRI-ERIC)
14:40	<b>A Patient Perspective on Rare Diseases</b> Deborah Mascalzoni (RD-Connect)

Brought together around 30 representatives from the European biological and medical science research infrastructures, policy makers, medical and health associations, industry representatives, patient advocacy groups, and other interested stakeholders.

# In the process to be consulted:





# CONTEXT



Legal texts are not easily accessible to non-lawyers. By developing codes of conduct that are as understandable as possible, we can help to guide researchers and administrative staff, reduce unnecessary fear about compliance and enhance data sharing for the sake of progress in research.



# PURPOSE

- To contribute to the proper application of the regulation, taking into account the specific features of processing personal data in the area of health;
- 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.



# SCOPE

This code of conduct aims to apply to data controllers who process personal data for purposes of scientific research in the area of health, e.g., researchers and research institutions, biobanks, health databases and registries.



# **BUILDING ON EXISTING CODES**

- **Most recent draft under GDPR:**
  - GÉANT Data Protection Code of Conduct
- **Relevant for our scope prior GDPR:**
  - IMI Code of Practice on Secondary Use of Medical Data in Scientific Research Projects
  - Code of practice for integrated user access to RD-Connect platform for health-related information and human biological samples



# **CONTENT AND TOPICS**



# Key Principles Art.5 GDPR

- Lawfulness, fairness and transparency
- Purpose limitation
- Data minimization
- Accuracy
- Storage limitation
- Integrity and confidentiality
- Accountability

# Processing of Data:

- Collection of data;
- Storage/archiving;
- Purpose of use;
- Reuse/access rules for the use of data by others;
- Transfer of data;
- Conditions for continuation of processing (death, legal incapacity).

# Conditions of Consent:

- Principles of consent (e.g., freely given, specific, informed, unambiguous);
- How specific must consent be;
- What are the appropriate safeguards when obtaining consent for e.g., for biobanking or big data use;
- Conditions for re-consent;
- Conditions for online consent;
- How to demonstrate proper use in accordance with consent limitations;
- Withdrawal of consent conditions and limits.

# Appropriate Safeguards:

- Data minimisation, e.g., pseudonymisation, anonymization of personal data;
- Governance, including ethical review;
- Special measures to treat sensitive data with special regard to biomaterial and genetic data;
- Conditions for transfer of data, including to third countries and international organizations.

# Rights of Data Subjects:

- Right of access to data;
- Right to know where and how data are stored and shared;
- Right of data portability, e.g., conditions for feeding back genetic data;
- Right to be forgotten;
- Right to object to processing for scientific, historical or statistical purposes.

# Protection of minors and vulnerable groups:

- Consent of minors;
- Consent and additional protection of other vulnerable groups;
- Profiling

# Governance of the Code

***Code is a living document!***

- Defining governing bodies
- Defining monitoring mechanisms



# PREPARATORY PROCEDURE



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)

3. Present and discuss results from sub-groups
  - Suggested format: online and/or in person discussions with stakeholders
  - Incorporate feedback
4. Prepare draft of the whole document and ensure public consultation
5. Code of Conduct proposal to be submitted to the EC (process yet to be defined)



# NEXT STEPS



**Minutes**

**TC in May**

Define involvement of experts

**7 June 2017**

Agree on procedure and topics



**THOUGHTS?**

# Contact

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