BBMRI-ERIC®

MAKING NEW TREATMENTS POSSIBLE

A CODE OF CONDUCT FOR HEALTH RESEARCH

OBJECTIVE OF THE GDPR
A CONTRAST

*"The General Data Protection Regulation **harmonises** the data protection rules in the European Union. The objectives of the Regulation are to reinforce data **protection rights of individuals**, facilitate the **free flow of personal data in the single market** and reduce administrative burden."*

CARTOON BY JAN ALBRECHT, MEP GDPR
Source: https://www.linkedin.com/pulse/brilliant-cartoon-video-explaining-gdpr-jan-albrecht-mep-kolah-ll-m/ (22 May 2018)

RESEARCH?

- Is the exception (Article 89)!
- Leaving room to MS derogations…
- …plethora of rules in practice
- WP29 and EDPB Guidelines!
- Adequacy decision (eg. UK or Japan)…
- Contractual Clauses (eg. US/NIH, universities)
- Article 40?

THE GAPS OF THE GDPR

- Seems a directive as it leaves a broad margin of intervention to States
- Legal basis to adopt for the purpose of health research is still fuzzy
- Some definitions remain unclear and some provisions are vague (e.g., purpose limitation or public interest)
- Does not prefer one measure of safeguard over the others
- Allows States maintain or introduce further conditions, including limitations with regard to the processing of special categories of data, such as health and genetic data (Art. 9.4)
- Does not clarify how the Clinical Trials Regulation (CTR) fits together with the GDPR in practice

CODE OF CONDUCTS

*"A **code of conduct** is a set of rules outlining the norms, rules, and responsibilities or proper practices of an individual party or an organisation."*

Source: Wikipedia

Potentially relevant for:

Individuals
Organisations
Sectors

Art. 40/41 GDPR specific:

- Assist GDPR compliance (clarity on accepted practices)
- Drafted bottom-up (sector-specific)
- Become soft law

§ 40 & 41 GDPR

- Art. 40.2 GDPR
Associations and other bodies representing categories of controllers or processors may prepare codes of conduct, or amend or extend such codes, for the purpose of **specifying the application of this Regulation**, such as with regard to:

(a) fair and transparent processing;
(b) the legitimate interests pursued by controllers in specific contexts;
(c) the collection of personal data;
(d) the pseudonymisation of personal data;
(e) the information provided to the public and to data subjects;
(f) the exercise of the rights of data subjects;
(g) the information provided to, and the protection of, children, and the manner in which the consent of the holders of parental responsibility over children is to be obtained;
(h) the measures and procedures referred to in Articles 24 and 25 and the measures to ensure security of processing referred to in Article 32;
(i) the notification of personal data breaches to supervisory authorities and the communication of such personal data breaches to data subjects;
(j) the transfer of personal data to third countries or international organisations; or
(k) out-of-court proceedings and other dispute resolution procedures for resolving disputes between controllers and data subjects with regard to processing, without prejudice to the rights of data subjects pursuant to Articles 77 and 79.

- Art. 40.9: the Commission may, by way of implementing acts, decide that the approved code of conduct, has general validity within the Union

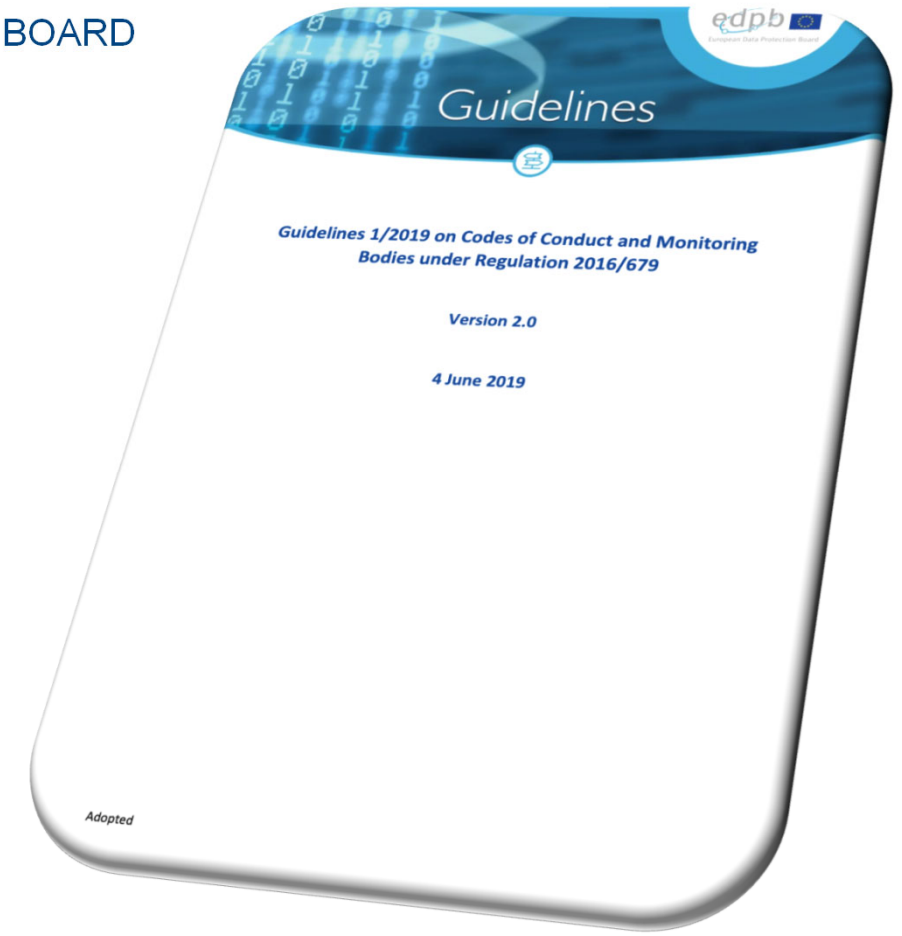
- Art. 41: monitoring accredited body

REQUIREMENTS PRIOR SUBMISSION

AS DEFINED BY THE EUROPEAN DATA PROTECTION BOARD

MUST HAVEs

- explanatory statement included;
- scope clearly defined;
- monitoring body identified;
- stakeholder consultation demonstrated;
- compliance with applicable national legislation confirmed;



REQUIREMENTS FOR APPROVAL

CONTENT-WISE

- meets a particular need of that sector (e.g. health research)
- facilitates the application of the GDPR;
- specifies the application of the GPDR;
- provides provides sufficient safeguards; and
- effective mechanisms for monitoring the compliance of the code

MONITORING BODY

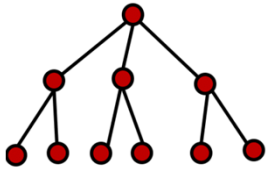
- independence;
- expertise;
- appropriate governance structures and procedures;
- transparent complaints handling; and
- review mechanisms.

SUBMISSION, APPROVAL & ACCEPTANCE

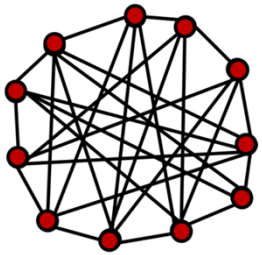
- Submission to a competent supervisory authority (typically national Data Protection Authority, DPA) that confirms European scope (transnationality) via cooperation procedure
- DPA will seek a maximum of two co-reviewers to assist with assessing the draft Code
- DPA will assist preparation for submission to the EDPB
- EDPB or DPA will communicate the decision to all SAs as per the consistency mechanisms procedure
- Prior final approval: possible that the DPA will approve or amend EDBP draft decision
- Approval

WHAT IS A EUROPEAN-WIDE CODE'S POTENTIAL?

- To contribute to the proper application of the Regulation in a practical, bottom-up, sector-specific, transparent, and potentially cost-effective manner
- To suggest harmonised understandings of how to read basic terms and implement requirements following practical standards
- To provide models for how to balance conflicting interests in the field of health research and thus contribute to a more aligned legislation and interpretation
- To provide for more practical guidance to close the gaps that legal acts normally must keep open
- To assist GDPR compliance
- To become soft law – approval by the EDPB and the Commission

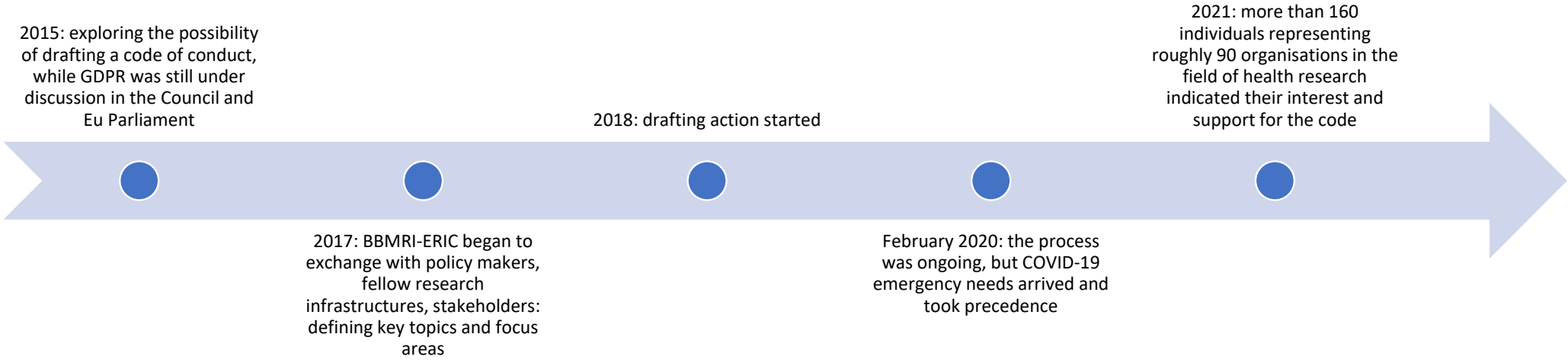


"Top-down"



"Bottom-up"

BBMRI-ERIC'S CODE INITIATIVE



- Covid-19 provided for some case studies for the code and pushed the willingness of stakeholders to contribute on the top of the list
- Now the code is a priority in the BBMRI-ERIC Work Programme 2021/2022

SCOPE

- Health research today takes place at the intersection of machine learning and health care; especially in relation to the secondary use of data.
- Our code initiative started with biobanks and extended to clinical trials, studies, cohorts, registries, genome databases' data for harmonized data sets. It also needs to consider links to patient(-owned) data and electronic health records.
- This contributes to the improvement of prevention, diagnosis, drug development and therapies to foster personalized medicine.

AIMS OF THE CODE

- Guiding researchers and administrative staff
- Reducing unnecessary fear relating to compliance
- Enhancing data sharing for the purpose of stimulating progress in research
- Fostering transparency for research participants and citizens in the handling of their data for research
- Being compatible to other codes (e.g., on clinical trial specific ones)

FOCUS AREAS AND KEY TOPICS

Focus areas

- ❑ Anonymous versus personal data
- ❑ Legal basis of processing
- ❑ Conditions of consent
- ❑ Responsibility of controller/processor and their relationship
- ❑ Appropriate Safeguards (esp. pseudonymization)
- ❑ Practical examples, references to existing guidelines

Key topics

- ❑ Fair and transparent processing
- ❑ Legitimate interests pursued by controllers in specific contexts
- ❑ Collection of personal data; pseudonymisation of personal data
- ❑ Information provided to individuals and the exercise of individuals' rights
- ❑ Information provided to and the protection of children
- ❑ Technical and organisational measures, including data protection by design and by default and security measures
- ❑ Breach notification
- ❑ Data transfers outside the EU
- ❑ Dispute resolution procedures

STRUCTURE

Non-legalistic language on questions that arise in the workflow for a researcher/data controller (FAQ style):

1.Question
1.1.Rule/Recommendation
1.2 Explanation
1.3 Example

THE DEVELOPMENT PROCESS

TABLE OF CONTENTS - CHAPTERS

COLLABORATION WITH OTHER CODE INITIATIVES

Previous initiatives:

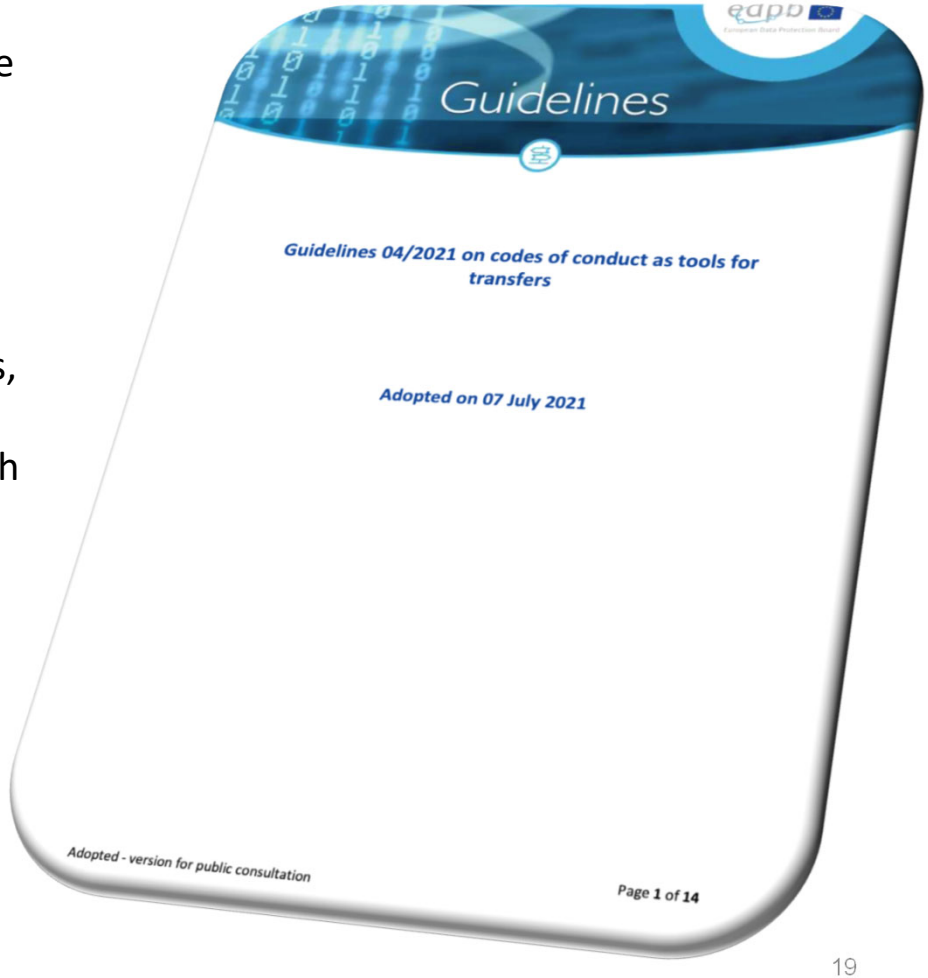
- IMI Code of Practice on Secondary Use of Medical Data in Scientific Projects (2014): never approved by policy makers, but a reference document for the research community
- Code of Conduct for User Access to the RD-Connect Genome-Phenome Analysis Platform (GPAP) for Health-related Information (2014, revised 2018)

Currently:

- Autumn 2019, a joint meeting with national or sectoral EU-wide code initiatives from Italy, the Netherlands, Norway, Belgium, Poland, but also GEANT, ESOMAR and EUCROF took place
- BBMRI's Code of Conduct is supposed to be more comprehensive in terms of content and focusing on health research as a whole
- National initiatives: Poland…
- other codes (European Federation of Pharmaceutical Industries and Associations (EFPIA)'s code of conduct on scientific research (including clinical trials), European CRO Federation's GDPR Code of Conduct for Service Providers in Clinical Research (EUCROF GDPR Code or Code) …) are under submission to national authorities: they are complementary

GUIDELINES FOR PUBLIC CONSULTATION

- EDPB Guidelines 4/2021 specify the application of Article 40-3 GDPR relating to codes of conduct as appropriate safeguards for transfers of personal data to third countries
- Provide practical guidance to code owners who seek approval for a code of conduct intended to be used as a tool for transfers: guidance on the content of such codes, their adoption process and the actors involved
- complement the EDPB Guidelines 1/2019 which establish the general framework for the adoption of codes of conduct
- BBMRI-ERIC welcomes these guidelines (1st October 2021)



A LONG ROAD AHEAD
WORTH TAKING

Although the goal remains for the coming months to come to submit a code for approval to the European level, much has already been achieved along the process.

It is a long road ahead, but certainly worth taking.

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INTERESTED? GET IN TOUCH!

Ilaria Colussi, ilaria.colussi@bbmri-eric.eu
Michaela Th. Mayrhofer, michaela.th.mayrhofer@bbmri-eric.eu
Irene Schluender, irene.schluender@bbmri-eric.eu

codeofconduct@bbmri-eric.eu
www.bbmri-eric.eu
@BBMRIERIC
BBMRI-ERIC