SSHOC workshop: SSH Code of Conduct

17 March 2021 - 14:00 to 16:30 CET - Online

Mathilde Steinsvåg Hansen & Ina Nepstad,
NSD – Norwegian Centre for Research Data
Michaela Th. Mayrhofer, BBMRI-ERIC

Introduction

Mathilde Steinsvåg Hansen,
Advisor, NSD

This project is funded from the EU Horizon 2020 Research and Innovation Programme (2014-2020) under Grant Agreement No. 823782

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Project: SSHOC
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Horizon 2020
European Union Funding
for Research & Innovation

Type of action & funding:
Research and Innovation action
(INFRAEOSC-04-2018)

Partners: 48
(23 beneficiaries + 25 LTPs)

SSH ESFRI Landmarks and Projects
& international SSH data infrastructures

Duration: 40 months
(January 2019 – 30 April 2022)

Project budget:
€ 14,455,594.08

Project website:
www.SSHOpenCloud.eu

Objectives:

- creating the social sciences and humanities **(SSH)** part of European Open Science Cloud **(EOSC)**
- maximising **re-use** through **Open Science** and **FAIR** principles (standards, common catalogue, access control, semantic techniques, training)
- interconnecting existing and new infrastructures (clustered cloud infrastructure)
- establishing appropriate **governance model** for SSH-EOSC

Social Sciences & Humanities Open Cloud

- SSHOC will create the social science and humanities area of the European Open Science Cloud (EOSC), thereby facilitating access to flexible, scalable research data and related services streamlined to the precise needs of the SSH community

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The purpose and the relation to further work.

Today we will get insights on experiences about codes of conducts, offering the opportunity to discuss the need for code of conducts, and possible challenges and experiences regarding establishments of code of conducts.

The discussions will be incorporated in the work of a further SSHOC task, *namely to initiate a Code of Conduct for Social Sciences and Humanities*.

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The agenda

14.00- 14.15: Welcome and about the workshop

14.15 – 14.25: A short presentation of findings in a SSHOC report – by Ina at NSD

14.25 – 14.35: A short presentation of what a code of conduct is and it`s relevance – by Mathilde at NSD

14:35 – 15.05: A presentation from BBMRI ERIC`s work on a code of conduct, by Michaela at BBMRI ERIC.

15.05 – 15.20: Questions to BBMRI ERIC.

15.20 – 15.30: Break

15.30 – 16.10: Discussion groups.

16.10 – 16.15: Break

16.15 – 16.30: Summary of discussions

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Presentation of findings from SSHOC report on the impact of the GDPR and its implications for EOSC

Ina Nepstad, PhD, Senior Advisor, NSD

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What is personal data?

Personal data means any information relating to an identified or identifiable person

rant Agreement No. 823782

What is processing?

Collecting and registering

Arranging and analysing

Transferring and storing

Publishing and archiving

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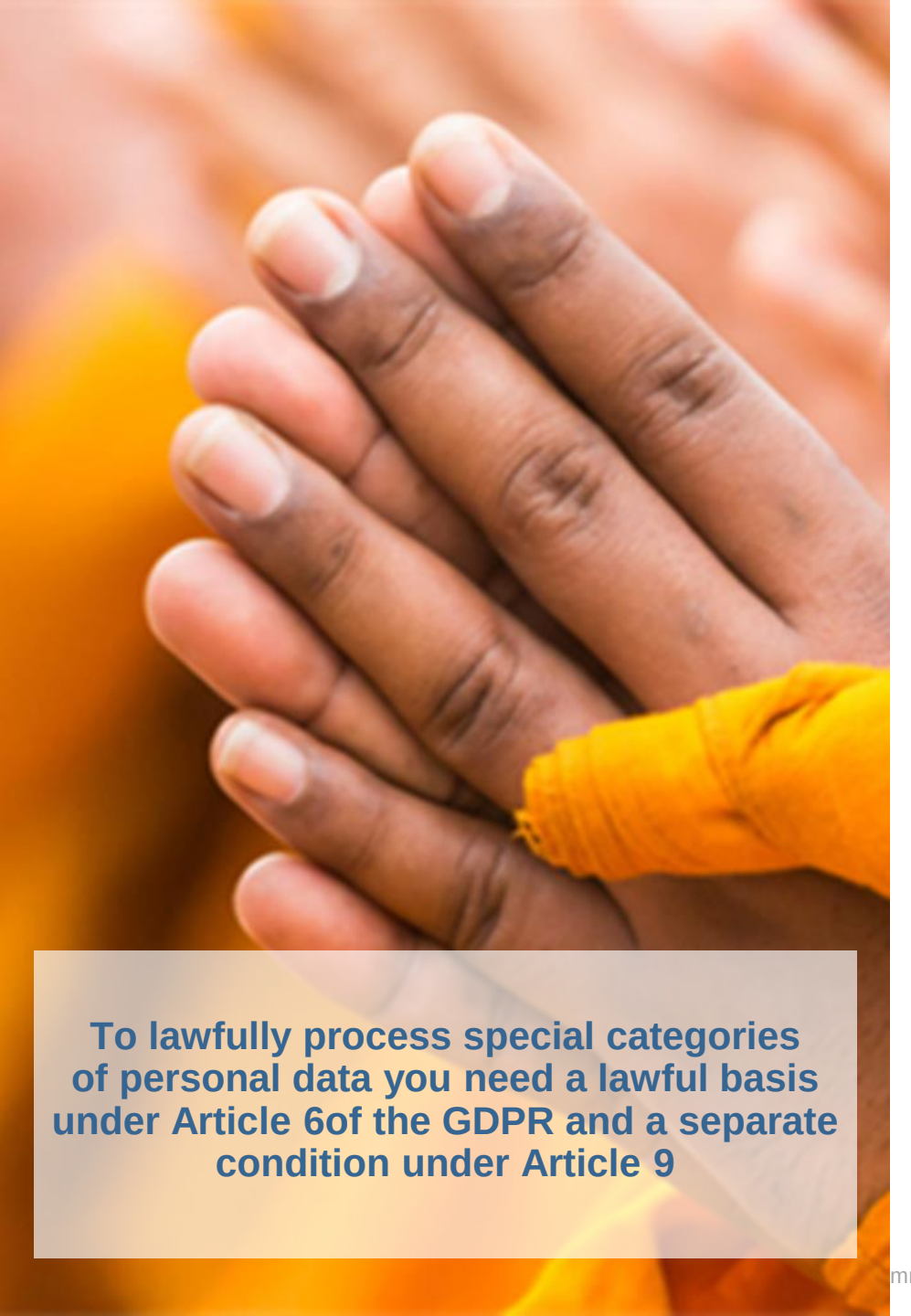
Deliverable 5.7
~~Report on~~ the impact of the GDPR and its implications for EOSC

This project is funded from the EU Horizon 2020 Research



To lawfully process special categories of personal data you need a lawful basis under Article 6of the GDPR and a separate condition under Article 9

Processing of special categories of personal data

"Processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject"

Article 9.2 (j)

mme (2014-2020) under Grant Agreement No. 823782

A supplementary provision in the GDPR

"...processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller..."

Art. 6 no .1 e

Appropriate safeguards pursuant to Article 89.1

"Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be sbject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject..."

A common understanding as to what measures will satisfy the requirement of appropriate measures pursuant to Articles 89.1 and 9.2 (j), would make sharing of research data across borders easier

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The GDPRs implications for EOSC

As all processing of personal data must have a legal ground, the different interpretations and supplementations in national legislations might affect the users of EOSC

The wording in the consent given from the data subject to the researcher might cause hinders for sharing data with others, including through EOSC

The required safety measures differ from one country to another. When organizing EOSC, a plan should be made for the assessment of safety measures for receiving data

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Concluding remarks

Further support of harmonization and consistent implementation of the GDPR across the EU is warranted

The terms and conditions for processing sensitive personal data varies from one country to another, but the common denominator in most countries is the importance of ensuring that the processing of special categories of personal data is subject to adequate safeguards, cf. Article 89 (1)

A mutual understanding as to what measures will satisfy the requirement of appropriate measures (“suitable, specific, technical, organizational”) pursuant to Article 89 (1), would make sharing of research data across borders easier

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A code of conduct

What is it and why is it necessary?

Mathilde Steinsvåg Hansen,
Advisor, NSD

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What is a code of conduct

- A set of voluntary accountability tools/guidelines which set out specific data protection rules for categories of controllers and processsors. A Code therefore assists members of the specific Code with data protection compliance and accountability.
- The code will be applicable in specific sectors or relating to particular processing operations (research).
- It identifies and resolve key data protection challenges that are important to the sector (research), with ensurance from supervision authorities that the code is appropriate.
- A code is written by an organisation representing a sector in a way that the sector understands and enables the sector to solve these challenges.
- Regulated in GDPR art. 40 and 41.

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Why code of conducts are relevant

- It will help the sector to be in compliance with GDPR
- They can be useful and effective accountability tools, providing a detailed description of what the most appropriate, legal and ethical set of behaviours of a sector. From a data protection viewpoint, code can therefore operate as a rulebook for controllers and processors who design and implement GDPR compliant data processing activities.
- Developing a code of conduct can help build public trust and confidence in the concrete sector`s ability to comply with data protection laws.
- It can help you reflect on your processing activities and ensure you follow rules designed for your sector to achive best practice
- Creation of codes might be potentially cost effective

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What should a code of conduct address?

- Code of conducts should help you to comply with GDPR, and should therefore cover topics as regulated in GDPR.
- The GDPR art. 40 has provided a non-exhaustive list containing topics to be addressed.
- The EDPB has issued guidelies for code of conducts,
  cf. https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_201901_v2.0_codesofconduct_en.pdf

  Among other things, EDPB states the criterias for adpoting/approving a Code.

- The discussion groups later today.

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TOWARDS A CODE OF CONDUCT FOR HEALTH RESEARCH

MICHAELA TH MAYRHOFER

17.03.2021

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.

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."*

Wikipedia

§ 40 GDPR

2) …such as with regard to:

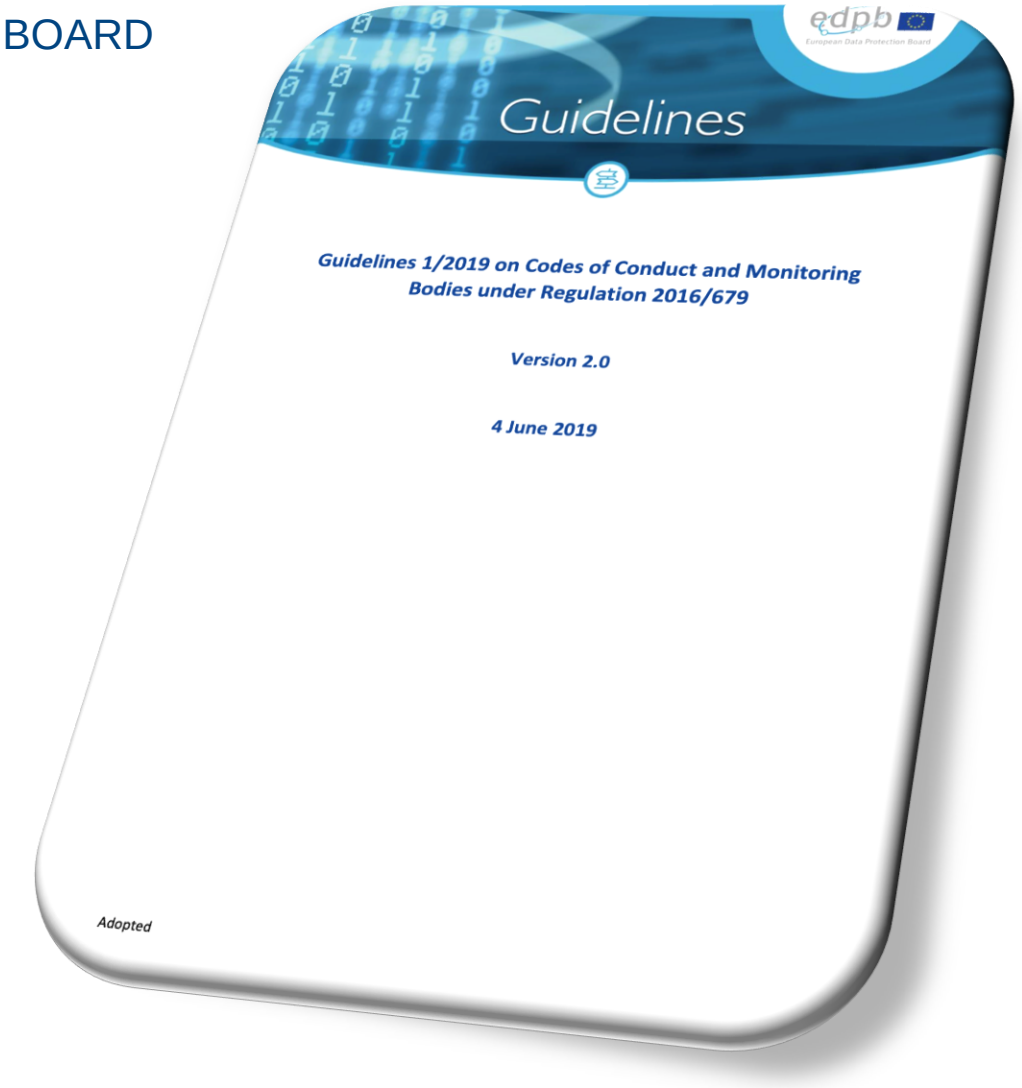
a) fair and transparent processing;
b) the legitimate interests pursued by controllers in specific contexts;
c) the collection of personal data;
d) the pseudonymisation of personal data;
e) the information provided to the public and to data subjects;
f) the exercise of the rights of data subjects;
g) 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.

REQUIREMENTS PRIOR SUBMISSION

AS DEFINED BY THE EUROPEAN DATA PROTECTION BOARD

MUST HAVE'S

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



MONITORING BODY

REQUIRED

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

CRITERIA FOR APPROVAL

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

SUBMISSION, APPROVAL & ACCEPTANCE

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

LEVELS OF INVOLVEMENT

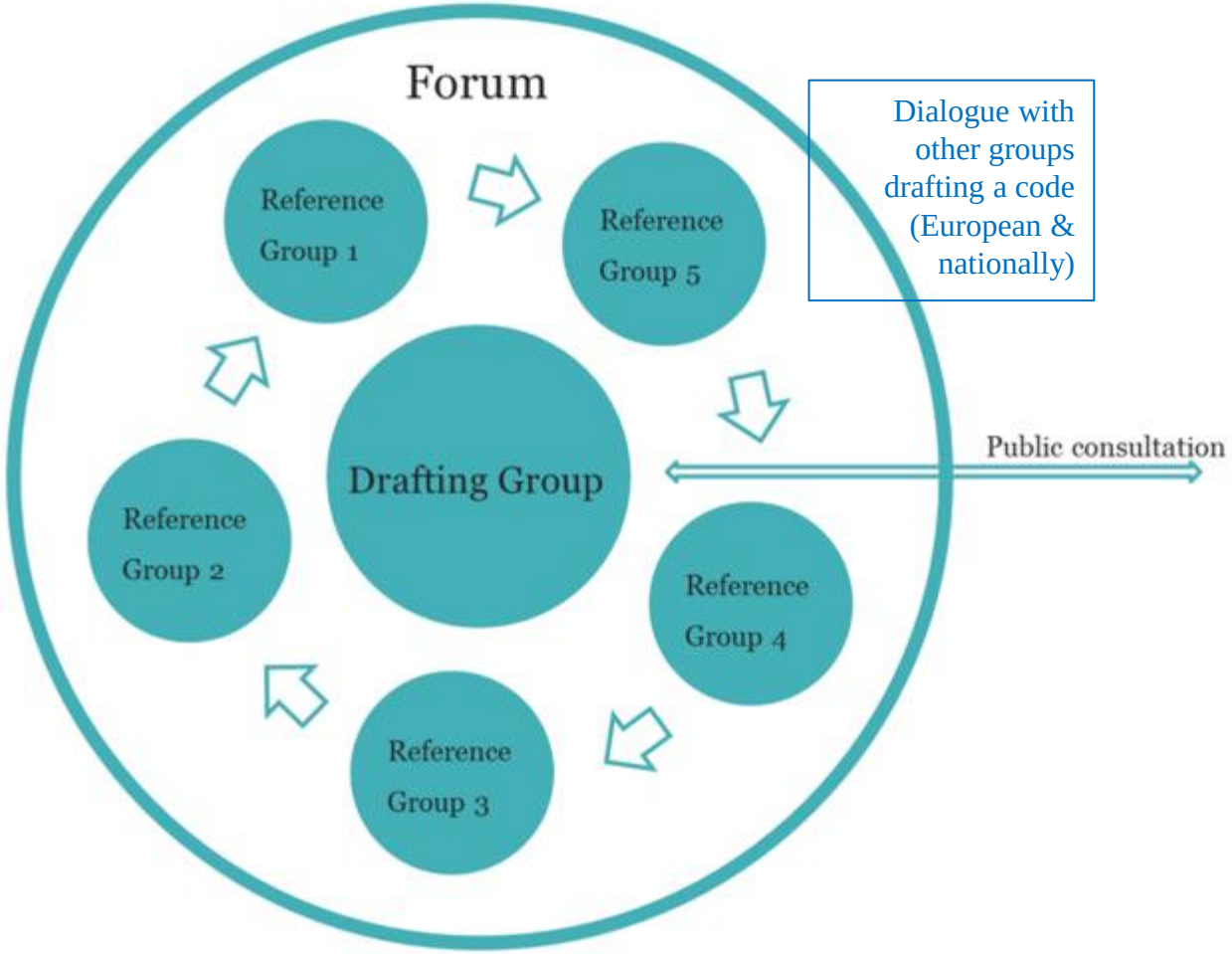
2017-2020

Forum: comprised oaf 350+ individuals & 90+ organizations interested in the Code's aims.

Drafting Group: Members provide legal and research expertise and experience in the field. Representatives from:

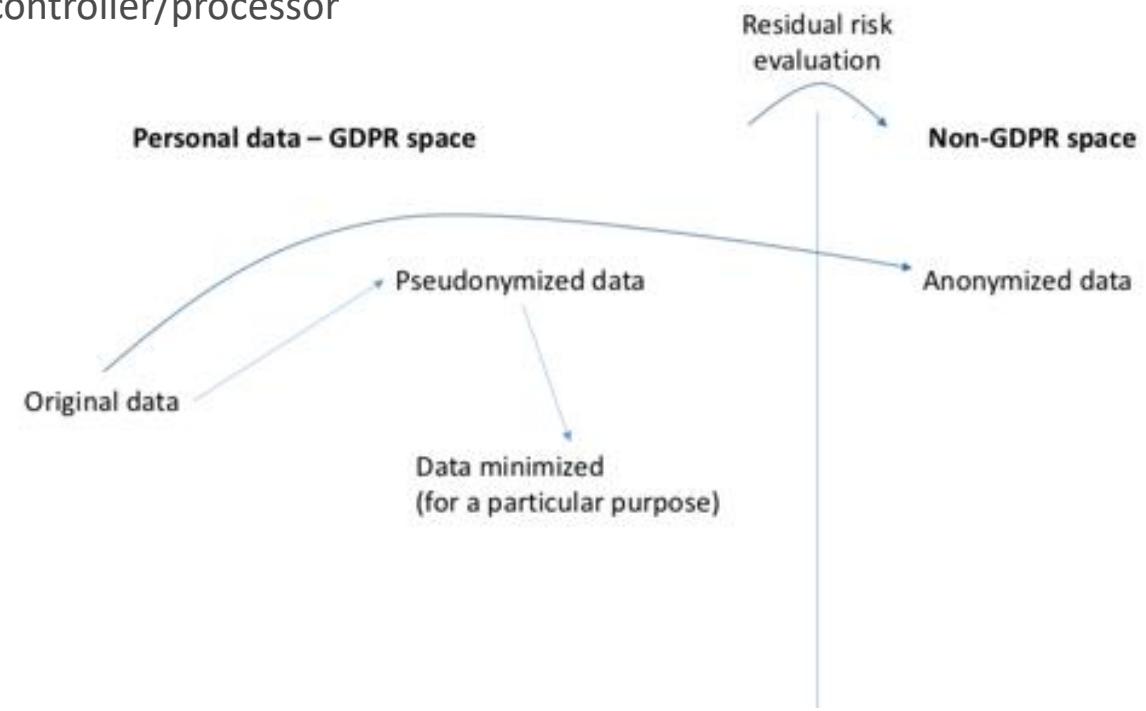
- All European biomedical science research infrastructures RIs
- Pharma industry
- European patient advocacy groups,
- European Medical associations,
- International Organizations

Reference Groups: include experts consulted on an ad-hoc basis to inform the drafting of specific sections.



KEY TOPICS

- Legal basis/consent
- Personal data/anonymisation
- Controller/joint controller/processor



- Our code does not promote one legal basis over another, as the decision is context dependent and might have a specification in national law (country derogation).
- Anonymisation: context dependent

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

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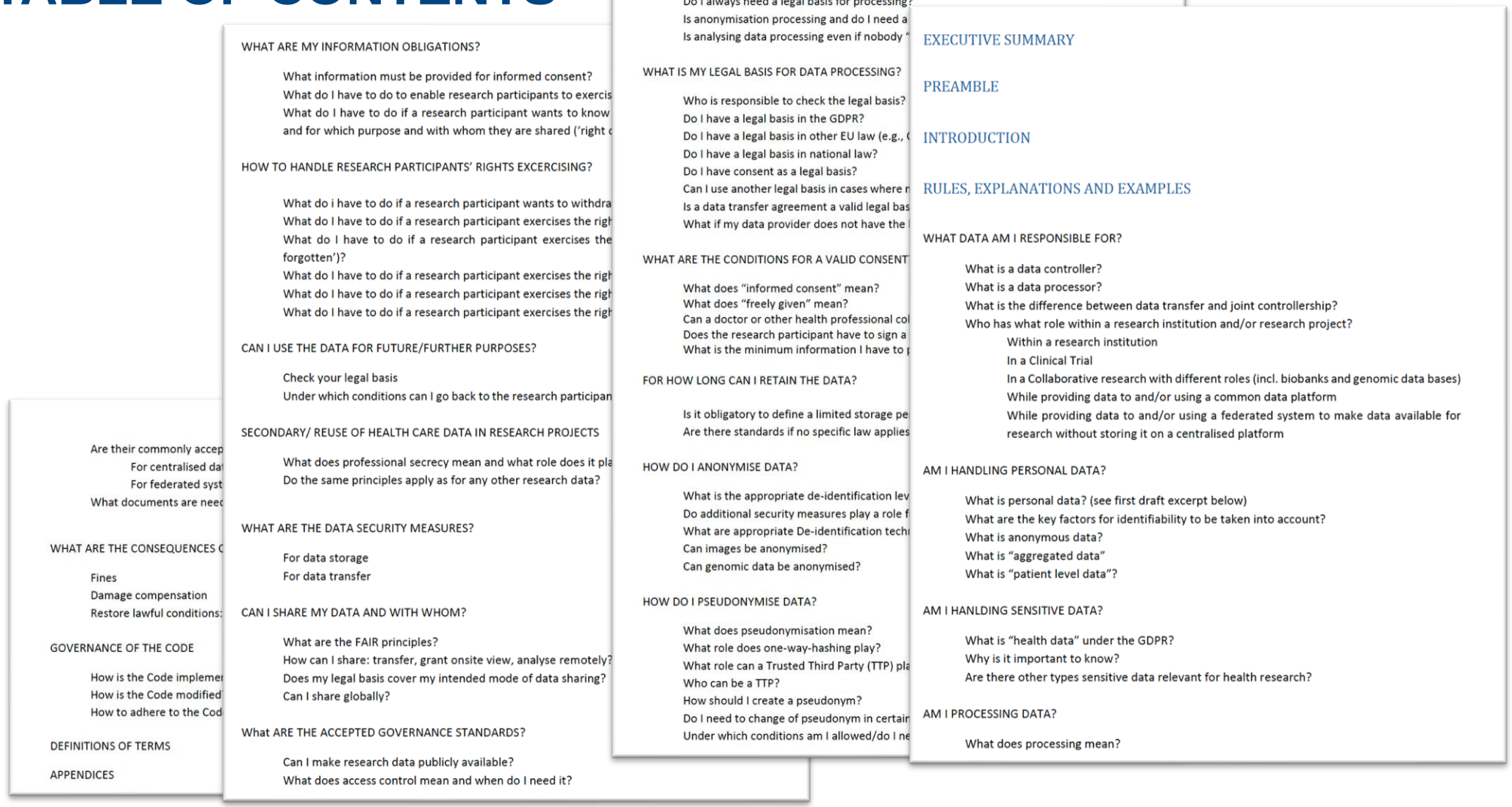

EXAMPLE: PERSONAL DATA

Rule: Data may (only) qualify as personal data due to additional information, that is available for identification.

Explanation: The status of data as personal data depends on who gets to know the data and what other information is available to him.

Example: The name “Peter Smith” is not enough information to identify somebody globally, but it would be sufficient in a classroom.

The same research data set might be considered anonymous, if access is controlled and the data only available for research projects, which have undergone an ethical scrutiny, whereas it might be considered personal data, if it is published in an open access database on the web. This is due to the fact, that the more people have access to data, the more likely it is, that some people with additional information or other means for identification at hand will access them.

JOINING FORCES WITH OTHER COMPLEMENTARY CODES

1./2. OCTOBER 2019, BRUSSELS

- **ESOMAR's Code of Conduct** for the market, opinion and social research and data analytics sector aims to harmonise ethical & operational requirements in Europe covering all kinds of market, social and opinion research.
- **EUCROF** is a non-profit entity representing the interests of CROs in Europe and prepares a code of conduct for 'service providers' (e.g., classical CRO's and IT solution vendors).
- **GEANT Code of Conduct** describes an approach to meet the requirements of the EU Data Protection Directive in federated identity management.
- **National code initiatives from NL, NO, BE, PL, IT, SP.**

EXPERT & PUBLIC CONSULTATIONS

Step 1: expert consultations on sections on an individual level (esp. use cases on a case-by-case basis) - ongoing

Step 2: expert consultation on sections of the code via reference groups (several rounds) - launch Q3 2021

Step 3: public consultation on the code (expectantly 1 round) & submission after edits - 2022

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QUESTIONS? GET IN TOUCH!

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