ADOPT BBMRI-ERIC®
gateway for health

Code of Conduct for Health Research

Irene Schlünder and Deborah Mascalzoni

12 September 2017

Art. 40 GDPR

Codes of conduct

The Member States, the supervisory authorities, the Board and the Commission shall encourage the drawing up of codes of conduct intended to contribute to the proper application of this Regulation, taking account of the specific features of the various processing sectors and (…)

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 (…)

AIM

- clarifying and specifying certain rules of the GDPR for controllers who process personal data for purposes of scientific research in the area of health
- taking position on some open issues (“research privilege”, “broad” consent etc.)
- using non-legalistic language and providing examples

and thus

- fostering harmonisation and legal certainty in applying the GDPR
- helping demonstrate compliance by controllers and processors with the regulation
- fostering transparency and trust in the use of personal data in the area of health research

Topics to be addressed in the CODE

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 mininimisation, e.g., pseaudonymisation, 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 and research results;
- 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.

Which infrastructures are involved in the drafting?

Writing Group Members

BBMRI-ERIC: J-E. Litton, M. Mayrhofer, I. Schlünder, F. Molnar-Gabor

RD-Connect: D. Mascalzoni

ECRIN: M. Matei

EORTEC: M. Verlinden

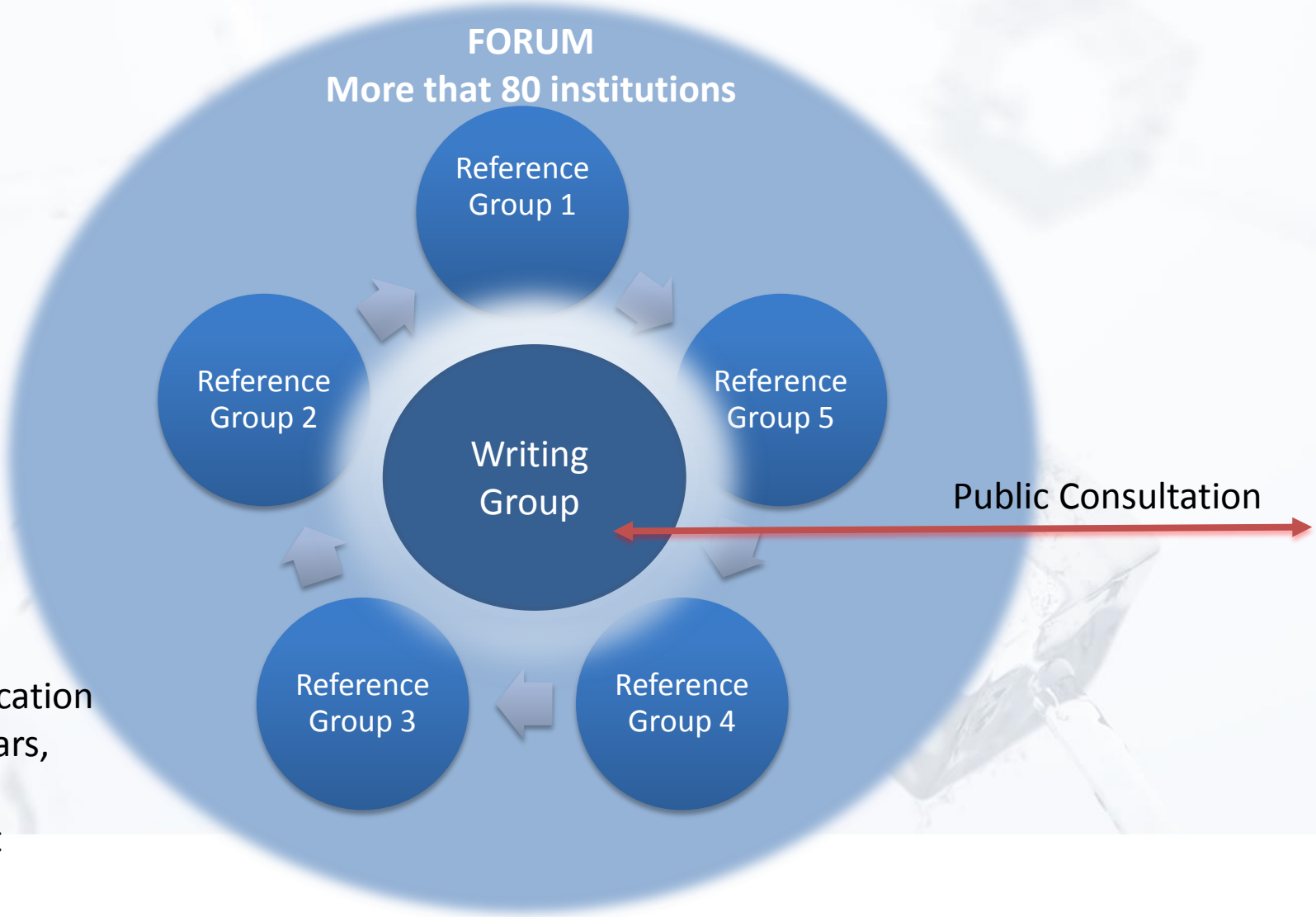
Stakeholder Forum: A. Kent

Global Alliance: D. Townend

EFPIA: A. Bahr (Sanofi), M. de la Paz (Novartis)

European Society of Radiology: C. Becker

Stakeholder's Involvement



Communication via webinars, website, mailinglist

WHAT HAPPENED SO FAR?

1 Feb 2017: BBMRI-ERIC Working Meeting:

The Road to a Health and Life Sciences GDPR Code of Conduct (Forum Meeting)

Presenting the idea

19 April 2017: Webinar on The Code of Conduct

Engaging further stakeholders.

7 June 2017: 1st Code of Conduct Forum Meeting

Agree on procedure and topics on a general level.

26-27 July 2017: 1st Writing Group Meeting

Discussing procedure & agreeing to assess IMI Code.

August/September 2017: Webinar of Writing Group

Discussing core topics

Timeline – Key Events

Writing Group

Monthly meetings (remotely & f2f)

2nd Forum meeting

November 2017 (date tbd)

Public Consultation

Spring 2018

www.code-of-conduct-for-health-research.eu

- online end of September –

Web: www.bbmri-eric.eu

@BBMRIERIC

BBMRI-ERIC