BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

Summary report following the BBMRI-ERIC working meeting on health and life sciences GDPR code of conduct

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ISC
Intelligence in Science

- WORKING MEETING MINUTES -

"SUMMARY REPORT FOLLOWING THE BBMRI-ERIC WORKING MEETING ON HEALTH AND LIFE SCIENCES GDPR CODE OF CONDUCT"

On 1 February 2017, the Biobanking and BioMolecular resources Research Infrastructure (hereafter: BBMRI-ERIC) held a working meeting in Brussels, bringing together around 30 representatives from the European biological and medical science research infrastructures, policy makers (European Commission's Directorate-General for Research & Innovation), medical and health associations, industry representatives, patient advocacy groups, and other interested stakeholders to discuss and develop on a roadmap for a harmonized health and life sciences General Data Protection Regulation (hereafter: GDPR) code of conduct and express commitment to be involved in the code development process.

1. Introduction

The implementation of the GDPR foresees, inter alia, in Article 40 the establishment of the codes of conduct for organizations to demonstrate compliance to the GDPR. The codes of conduct are encouraged as a means of contributing to the proper understanding and application of the regulation and may be prepared by associations or representative bodies for approval, registration, and publication by a supervisory authority, or – if data processing takes place cross-border – by the European Data Protection Board, with the European Commission deciding on and declaring the general validity of the codes across the EU. The compliance to the codes is to be monitored by accredited bodies.

Health and life sciences researchers rely heavily on the use of sensitive personal data, having specific characteristics, such as those relating to data subject rights and data processing and use, which the code of conduct aims to address in the context of health and medical research. In order to realize the potential of collaborative research and cross-border exchange of health-related data for the benefit of European citizens a coordinated and harmonized approach is therefore essential, especially in the light of possibly differing Member States' implementing approaches.

2. Working meeting proceedings

The working meeting began with a series of presentations in order to set the scene and introduce the topics.

The meeting was opened by **Jan-Eric Litton, Director General of BBMRI-ERIC**, who explained the vision of writing the code of conduct for health and life sciences. He said that while the GDPR provides general rules, it also means health research is not specifically addressed in it. He stated that there is a need to clarify the data-sharing rules and outlined some of the main concerns the code should address in a clear and understandable way, which are: conditions for consent, secondary processing of data, pseudonymisation, defining and dealing with genetic data, transfers to third countries, and processing in the cloud, specifically the European Open Science Cloud. He highlighted that these must be addressed in a way to be understood by the researchers as well citizens, rather than explained with science buzzwords or legalistic language. He also emphasized that such a code may offer greater sustainability, as opposed to project-based codes, which serve a certain consortium for a limited period of time. The code drafting team may, among others, comprise BBMRI-ERIC, ECRIN, EMBL (ELIXIR), EATRIS, Euro-BioImaging and other Research Infrastructures in CORBEL, furthermore EFPIA, EUREC, and patients' organizations, taking social and cultural differences, as well as expertise into account. He then presented the approval procedure – the code will be submitted to the competent data protection authority with a goal to be validated by the European Commission – as well as the envisioned timeline, which is further detailed below.

Irene Schlünder, BBMRI-ERIC, presented the experience in the wide-ranging process of developing the IMI code of practice on the secondary use of medical data in scientific research projects, which served to provide clarifications for implementation of data protection requirements, guidance for researchers and healthcare professionals (i.e. non-lawyers), and understandable and practical instructions, with respect to local exceptions. The issue of privacy was identified one of the most pressing issues in collaborative projects. The code was comprehensive and covered issues of secondary use, collection, use, and re-use of data, consent, de-identification and protection of anonymized data, re-contacting patients, data security, retention of records, and disclosure of data. The code was submitted to more than

one national data protection authority and discussed, but the procedure under the Data Protection Directive then got stuck due to the upcoming GDPR. She also stressed that in terms of implementation the code is not binding per se, that it can be accepted with a contract or declaration, it has to be regularly revised, and that it is to be complemented by best practices, standard operating procedures, etc. It could now serve as one starting point for the development of a Code of Conduct under the GDPR.

Brendan Barnes, EFPIA, talked about the industry perspective. He emphasized that EFPIA is concerned about harmonization aspect (vs. national interpretations) and that for them the core issue is the secondary use of data. Due to the fact that the Digital Single Market is one of EU's key initiatives, he said a regulatory structure for this needs to be in place; the GDPR is now adopted and there is a proposal on ePrivacy regulation, too. He expressed that a code of conduct can be beneficial for navigating this complex environment. He also touched upon the transformations the industry faces and their impacts, for example expansion in the range of the data used in evaluating medicines throughout the cycles. The GDPR invites the establishment of codes, bringing the issue of scope of such code to front, which in his opinion covers a lot. He mentioned the need that certain procedures, for example in the case of pseudonymization, should be endorsed by the authorities. He also mentioned stakeholder engagement and stressed that the code needs to meet the expectations of the people whose data we are using. Correspondingly, he said that relationship with the regulators is key.

Jasper Bovenberg, BBMRI-ERIC, gave an outline of the international perspective, with a specific focus on the transfer of personal data to the third countries. He first elaborated the general guiding principles and legal grounds for such transfers (informed consent, ad hoc clauses, adequacy decision, contractual clauses), and then explained that an approved code of conduct – as a structured approach to data transfers, with uniform rules, transparency, global reach, and by being a subject to monitoring and governance – is in the GDPR introduced as one of the mechanisms of legitimizing transfers of personal data to controllers and processors not subject to the GDPR (i.e. to third countries), in order to provide appropriate safeguards.

Deborah Mascalzoni, RD-Connect, offered the patient perspective on rare diseases. She presented the International charter of principles for sharing bio-specimens and data and the code of conduct in the FP7 Project RD-CONNECT, which, apart from the EU countries, also covers Australia and the NIH (the US). She emphasized that the charter is a result of careful negotiation of various stakeholders' interests, and that it tries to balance privacy against freedom of scientific enquiry. She also said that it has to be made clear that there is no guarantee of complete privacy. Then she brought informed consent to front with the following core elements to be included in consent, in the case of use of existing collections: international sharing, next generation sequencing, return of incidental findings, and creation of IPS cell lines. Finally, she presented their governance process for ensuring the proper data use and the corresponding checks and balances.

3. Tour the table session and discussion

The tour the table session, moderated by **Jasper Bovenberg, BBMRI-ERIC**, was intended to get the views and concerns on the part of ESFRI research infrastructures and other present stakeholders, in order to get a closer insight into impacts of data protection rules on processing of personal data in health and life sciences. First, **Mihaela Matei, ECRIN**, focused on the data sharing in the context of clinical trials and as topics to be included in the code listed sharing the patient data from the clinical trials with researchers from the US and working with the international partners in general and the issue of informed consent. **Dominik Reske, EMBL** [at the meeting *not* speaking on behalf of EMBL], sees the code of conduct as a vehicle to legitimize data transfers. He explained the nature of EMBL, which operates as an international organization, meaning the data protection rules affect them only indirectly and they are not subject to national oversight. In that context he emphasized the issue of access to justice for the data subjects. **Virginie Bros-Facer, EURORDIS**, expressed concerns regarding the secondary use of data, as this issue may be confusing for patients, which could be solved with information and capacity building. She also pointed out a need for a clear communication strategy and governance and implementation oversight, as trust is imperative to patients. Patients are nonetheless committed to sharing data for research. **Michiel Verlinden, EORTC**, stressed the distinction between clinical trials data, which are subject to extra conditions, and other health-related data, and discussed the data portability, as in their case they only process pseudonymized data and therefore cannot respect the right to data portability. **Deborah Mascalzoni, RD-Connect**, added that healthy volunteers' perspectives also need to be addressed and taken into account. **European Commission** had no statement regarding the concrete issues, but nevertheless said that code of conduct would be welcome and useful. Further discussants brought value of data to attention, with **David Townend, GA4GH/Maastricht University**, making a distinction between past or future value of data, with the latter being tied to quality, reusability, and interoperability of data, which in his opinion should be considered when speaking about the value of data.

4. A roadmap for the health and life sciences GDPR code of conduct

Michaela Th Mayrhofer, BBMRI-ERIC, summed up the meeting proceedings regarding the scope, key stakeholders, and purpose of the code, which includes offering clarity for researchers and harmonization, transparency to citizens, sustainability, trustworthiness, expectations management and developing communication efforts, and stressed that developing the code of conduct is a translation exercise, building on other prior initiatives. She also emphasized that the meeting is the first step of engaging stakeholders in the dialogue and involving them in the process of the code development. Among the key topics to be addressed, as summarized from the discussions, are the secondary use of data, third country data sharing, the issue of informed consent, health-related vs. clinical data, etc. She also reminded there is a need for establishing new or referring to already existing best practices and guidelines.

She then identified the next steps in the process: BBMRI-ERIC is to present a roadmap of the process (and how to get involved) for drafting the code to the stakeholders by the end of February. This has to be done by building on different levels of participation: information, consultation, dialogue, and partnership. The meeting was concluded by the common agreement that a code of conduct, its development, and a transparent consultation process is desirable. The timeline is aimed at having a first draft of the code of conduct ready in July 2017, followed by a public stakeholders' consultation in the period September-November 2017, arriving at an updated draft in December 2017. The goal is to have the code ready for submission for approval by 25 May 2018, when the GDPR will be applied from. She also pointed out that the parties involved in developing the code should consider which relevant lead supervisory authority to select, as presence in different Member States triggers the consistency mechanism in the GDPR.

The contact point is BBMRI-ERIC (jan-eric.litton@bbmri-eric.eu, Michaela.th.mayrhofer@bbmri-eric.eu), which coordinates this exercise.

Minutes prepared by:

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Annex: The final agenda

Time	
14:00	**Why do we need a Code of Conduct? What is at Stake?** Prof Jan-Eric Litton, Director General of BBMRI-ERIC
14:10	**The Experience in Developing IMI Code of Practice** Irene Schlünder (BBMRI-ERIC)
14:20	**An Industry Perspective** Brendan Barnes (EFPIA)
14:30	**An International Perspective** Jasper Bovenberg (BBMRI-ERIC)
14:40	**A Patient Perspective on Rare Diseases** Deborah Mascalzoni (RD-Connect)
14:55	**View from ESFRI Biological and Medical Sciences Research Infrastructures** Tour de table
15:35	**Open discussion** Moderation: Dr Michaela Mayrhofer (BBMRI-ERIC)
16:10	**Conclusions: A Roadmap for the Health and Life Science GDPR Code of Conduct** Steps towards a public consultation process: • Summing up • Next steps in developing a code of conduct • Identifying timeline, contact persons (who does what?) Minutes: Tjaša Petročnik (ISC)