

Press release:

**GDPR Code of Conduct for Health Research and Implications for FP9**

**6 November 2017, Brussels**

**Brussels, 9 October 2017 – The Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium (BBMRI-ERIC) is hosting a seminar to assess the impact of the GDPR on FP9 health research and examine how the Code of Conduct for Health Research being developed by BBMRI-ERIC and collaborators will address future health challenges. The seminar will take place on 6 November 2017 in Brussels.**

Preparations for FP9 (2021-2027) has begun and the European Commission is expected to publish its initial proposal in the first half of 2018. Discussions on the programme’s structure, content, and budget are under way covering sustainability, socio-economic impact, and the use and management of data created by pan-European research infrastructures, including the contribution of these infrastructures to health sciences and research. The General Data Protection Regulation (GDPR) will apply across the EU from 25 May 2018. Articles 40 and 41 of the GDPR are the primary sources of authority for establishing approved codes of conduct to serve as compliance tools for data controllers and processors. Following a series of exploratory meetings in 2017, BBMRI-ERIC has launched a forum to develop a GDPR Code of Conduct for Health Research as the means to comply and to contribute to the proper implementation of GDPR. Through the forum, BBMRI-ERIC is engaging with approximately 80 key stakeholders and a drafting group from across the EU, to outline the GDPR Code of Conduct for Health Research. This code will be vital for enabling and advancing collaborative health research following the application of the GDPR.

The seminar on 6 November 2017 will focus on how the new data protection environment will determine and affect the use of (sensitive) personal data for health sciences in future research collaborations. The seminar will also help participants to understand the policy context for FP9 and how this will be impacted by the GDPR and other regulations, including those covering medical devices and clinical trials. The seminar will also include discussions on how the programme might address biological and medical science research, including the use of sensitive personal data, for the programme to deliver benefits for the EU’s citizens and economy.

The seminar sessions will cover big data and the European Open Science Cloud, GDPR and the Code of Conduct for Health Research, and FP9. Speakers will include:

* Jan-Eric Litton, Senior Advisor, BBRMRI-ERIC;
* Michaela Th. Mayrhofer, Chief Policy Officer, BBMRI-ERIC;
* Augusto Burgueno Arjona, Head of Unit, European Commission;
* Magali Poinot, Advisor to the Executive Director, IMI2;
* Brendan Barnes, Director Data protection, IP & Global Health, EFPIA;
* Lydia Makaroff, Director, European Cancer Patient Coalition;
* Nathalie Bertels, Big Data Value Association.

**The seminar will take place on** Monday, 6 November 2017, from 10h00 to 16h00 at Science 14, 14b Rue de la Science, Brussels B-1040 (map: <https://goo.gl/maps/6DQhCYURwrQ2>).

**Registration is available is available at** <http://iscintelligence.com/event.php?id=322>.

**For further information on the 6 November seminar, please contact:**

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**Editor’s note**

**Previous meetings on the GDPR Code of Conduct for Health Research**:

Implementation of the General Data Protection Regulation (GDPR), which will apply from 25 May 2018, will encourage EU organisations to draw up a code(s) of conduct so that they can contribute to the proper application of the GDPR in specific sectors and can demonstrate compliance with the GDPR. A code(s) may be prepared by associations or representative bodies for the approval, registration, and publication by a supervisory authority.

The GDPR Code of Conduct for Health Research will help guide researchers and administrative staff, will reduce unnecessary fear about compliance, and enhance data sharing for the progress of health research.

Since early 2017, BBMRI-ERIC has held multiple working meetings on this topic.

On 1 February 2017, BBMRI-ERIC hosted a working meeting in Brussels, bringing 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. The aim was to express commitment to be involved in developing the code as well as to discuss and develop a roadmap for a harmonised Code of Conduct for Health Research. The February meeting concluded with a common agreement that it would be good to develop a code of conduct and to have a transparent consultation process. More information is available at: <http://iscintelligence.com/event.php?id=310>.

On 7 June 2017, in Brussels, BBMRI-ERIC organized a forum to present the governance concept and a timeline for a BBMRI-ERIC Code of Conduct for Health Research, to discuss the needs of patients and Member States, and the perspectives of third countries/international organisations, and to outline the code’s topics and working groups. More information is available at: <http://iscintelligence.com/event.php?id=319>. While the previous meetings were aimed at discussing the priority issues that need to be addressed by the code and agreeing on its development timeline, a subsequent meeting in Brussels on 26-27 July 2017 brought together the core drafting group to prepare the text of the code. In autumn 2017, this text will be discussed with reference groups and consulted on with the Code of Conduct forum members.

The drafting group for the Code of Conduct for Health Research comprises BBMRI-ERIC (lead), representing CORBEL (the EU project of BMS RIs), ECRIN, representatives from EFPIA, CESSDA, RD-CONNECT, Global Alliance, ESR and others, taking into account social and cultural differences, as well as expertise.

**BBMRI-ERIC:**

BBMRI-ERIC (<http://bbmri-eric.eu/>) is a pan-European research infrastructure which provides access to quality-controlled human biological samples, such as blood, tissues, cells or DNA, and associated clinical and research data. It aims to establish, operate and develop a pan-European distributed research infrastructure of biobanks and biomolecular resources to facilitate the access to resources as well as facilities and to support high-quality biomolecular and medical research. BBMRI-ERIC comprises 19 member states and one international organisation, making it one of the largest research infrastructures for health research in Europe.