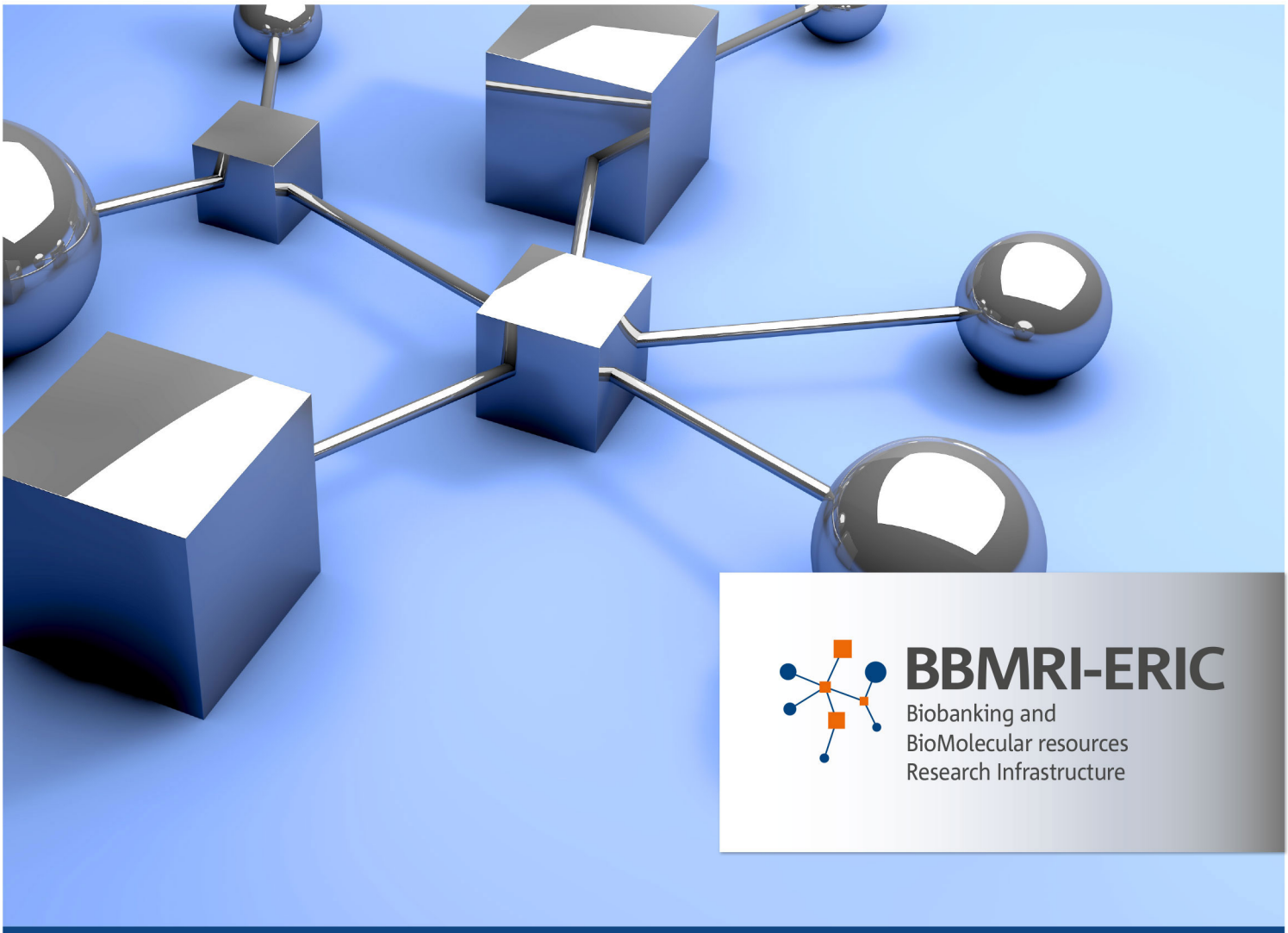

BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

POSITION PAPER

ON THE

GENERAL DATA PROTECTON REGULATION

October 2015

Contents

Executive Summary

Seventeen European Member States and one International Organisation (IARC) have joined forces in establishing the Biobanking and BioMolecular resources Research Infrastructure –European Research Infrastructure Consortium (BBMRI-ERIC). As of 3 December 2013, BBMRI-ERIC is an international organization established under EU law, facilitating access to biological resources as well as biomedical facilities. The specific legal form of an ERIC is designed to facilitate the joint establishment and operation of research infrastructures of European interest in the European Research Area (ERA).

BBMRI-ERIC acknowledges and embraces the dynamic potential of the General Data Protection Regulation for the ERA. At the same time, wrongly aimed provisions could seriously hamper pan-European research as well. Building on the Day of Action led by BBMRI-ERIC on 16 June 2015, which led to a set of concise recommendations on the General Data Protection Regulation,[1] this position paper further elucidates and illustrates these recommendations. BBMRI-ERIC urges that the following concerns of the European research community are taken into account in the ongoing legislative process and is prepared to enter in a dialogue with policymakers on the following issues:

- Safeguard the Interests of Patients in Medical Research

Patients have a legitimate expectation in an increase of knowledge, as recognised by Council and Parliament in Recital 88. For this reason, **the Regulation should safeguard the interests of patients in medical research.** Future research purposes are often impossible to predict. A legal requirement for patients to reconsent often for novel forms of research is therefore encumbering for both the researcher and the patients. While protecting the data from misuse and illegal disclosure, the Regulation should also ensure that samples and data do not go to waste. **Patients should therefore have a right to consent to the inclusion of their data and biomaterials to biobanks and databases for biomedical research**, even if potential research objectives cannot be stated as specifically as in a concrete clinical study.

We propose that the message of Recital 25 aa (Council version) must be maintained.

- Maintain the Distinction Between Processing of Personal Data for Scientific Research Purposes and Other Forms of Processing

Biomedical research aims at furthering our knowledge of human health and developing new treatments and therapies to counter disease. For this reason, **all biomedical research can be considered a substantive public interest**. Ensuring that this remains so requires drawing a line between processing for scientific research purposes and processing for other purposes, such as direct marketing and personal profiling of clients, as follows from Parliament's and Council's amendments to Recital 126. A number of parliamentary amendments go one step further however, raising the barriers for research too high through wordings such as 'high public interest' and allowing processing for research using non-anonymous health data only if that research 'cannot possibly be carried out otherwise'. We urge you to replace 'possibly' with 'reasonably'. Finally, we should note that **a number of novel data subject rights proposed in the GDPR are already routinely offered in research, such as the right to object**.

[1] http://bbmri-eric.eu/documents/10181/125935/Position+Paper+Day+of+Action+Data+for+Health+and+Science+Final.pdf/.

We approve of the amendments to Recital 126 (Parliamentary amendments and Council version). At the same time, we are concerned about the term 'high public interest' in Parliamentary amendments for Recital 123a and Article 81(2a) (a.o.) and urge a change to 'public interest'. We are also concerned that amendments to Articles 81(2a) and 83(1b) (Parliament version), stating that data processing involve pseudonymisation 'under the highest technical standards', will prove severely detrimental to research and urge a wording such as 'reasonably high' standards. We consider some of the derogations for processing data for scientific research purposes as envisaged by the Council in Article 83 to be more far reaching than strictly necessary. In particular, a derogation for Article 19 could be omitted.

- Harmonised Rules Are Preferable to Promote Pan-European Research

Consistent harmonised rules for research at EU level are needed to promote research collaboration Europe-wide. Harmonised data protection rules for research, which take the perspective of pan-European research into account are urgently needed, particularly in rare disease research. The opportunity to develop sector-specific rules under the aegis of the GDPR is one way of furthering harmonisation. Given the ambitions of the European Union to strengthen the development of a European Research Area, **pan-European organisations such as BBMRI-ERIC should also have a right to submit Codes of Conduct directly to the EU Data Protection Board.**

We appreciate the opportunity for associations and other bodies representing categories of controllers or processors to draw up codes of conduct (Art. 38) and envisage a future role for BBMRI-ERIC in this process. However, European organisations such as BBMRI-ERIC should also have the right to submit codes of conduct directly for approval to the EU Data Protection Board. Article 38 para 2 should therefore be amended as follows: 'ERICS and other European research networks or organisations representing more than three Member States shall submit the draft code of conduct directly to the European Data Protection Board.'

- Member State-Specific Derogations for Processing Personal Data for Scientific Research Purposes Remain Important

Currently, many Member States' research and research infrastructures are operating on the basis of specific derogations and interpretations of the Data Protection Directive. **Such derogations should not be used by Member States or competent authorities such as funding agencies and ethics committees to block cross-border research and exchange of personal data for research purposes.** At the same time, achieving full harmonisation for health research through the General Data Protection Regulation would be too ambitious a goal. **The General Data Protection Regulation should leave sufficient leeway for Member State-specific approaches** in the absence of harmonised health systems. Ideally, established national and international legislative frameworks, guidelines and codes of conduct relating to scientific research should be acknowledged specifically in Article 83.

Therefore, maintain specific exemptions for processing of special categories of personal data, including genetic data and data concerning health, for purposes of scientific research in Article 9 para 2(i) (Council version) and Article 83, including Member State-specific derogations for the requirement of consent. Make sure that Member State-specific derogations are not invoked to block, delay or otherwise unduly frustrate cross-border data exchange for research purposes. Therefore make the derogation clause consistent by introducing specific safeguards in Article 83, as indicated in Article 9 para 2 (i). In addition, established national and international legislative frameworks, guidelines and codes of conduct relating to scientific research should be acknowledged specifically in Article 83.

Making the Case for Biobanking Across Europe

Seventeen European Member States and one International Organisation (IARC) have joined forces in establishing the Biobanking and BioMolecular resources Research Infrastructure –European Research Infrastructure Consortium (BBMRI-ERIC). As of 3 December 2013, BBMRI-ERIC is an international organization established under EU law, facilitating access to biological resources as well as biomedical facilities. It relies on a close collaboration with numerous stakeholders from research, biobanking, patient advocacy groups, and the pharmaceutical and biotech industry. The specific legal form of an ERIC is designed to facilitate the joint establishment and operation of research infrastructures of European interest in the European Research Area (ERA).

As the proper consideration of ethical, legal and social issues (ELSI) is crucial to any biobanking activity, the Common Service ELSI is considered a key asset of BBMRI-ERIC. Established in February 2015, the Common Service ELSI aims to facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices.

BBMRI-ERIC acknowledges and embraces the dynamic potential of the General Data Protection Regulation for the European Research Area (ERA). In order to achieve reliable and reproducible results, health research depends on high quality samples and Big Data, which will often need to be shared across borders in order to achieve the best. The GDPR could greatly ease transnational health research and cross-border exchange of data to further biomedical innovation for the benefit and wellbeing for European citizens and patients. At the same time, wrongly aimed provisions could seriously hamper pan-European research as well.

A Day of Action led by BBMRI-ERIC was organised on 16 June 2015 with the aim of alerting EU policy-makers to the harmful effects the General Data Protection Regulation could have on statistical, scientific, and historical research and healthcare if restrictions, including a requirement for overly specific consent with only a narrow exception in science and health research, are introduced.[2] Participating organisations urged EU policy-makers to recognise the technical and ethical safeguards, which already exist in research and to ensure that research and healthcare are not hindered by the General Data Protection Regulation. These led to a set of concise recommendations to the General Data Protection Regulation.[3]

This position paper, drawn up by a team of experts from multiple Member States[4] in consultation with other members of the Common Service ELSI, builds on and further elucidates and illustrates these recommendations. BBMRI-ERIC urges that the following concerns of the European research community are taken into account in the ongoing legislative process and is prepared to enter in a dialogue with policymakers on these topics.

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[2] http://www.nature.com/news/data-overprotection-1.17825.

[3] http://bbmri-eric.eu/documents/10181/125935/Position+Paper+Day+of+Action+Data+for+Health+and+Science+Final.pdf/.

[4] In particular Ruth Baldacchino (BBMRI.mt), Martin Boeckhout (BBMRI.nl), Gauthier Chassang (BBMRI.fr), Michaela Th. Mayrhofer (BBMRI-ERIC), Jane Reichel (BBMRI.se), Irene Schlünder (BBMRI.de) and Olga Tzortzatou (BBMRI.gr). A full list of the members of the Common Service ELSI is availabe at http://www.bbmri-eric.eu/common-services.

1. Safeguard the Interests of Patients in Medical Research

Concrete proposal

Maintain the message of Recital 25 aa (Council version).

Explanation

Patients have a legitimate expectation in an increase of knowledge, as recognised by Council and Parliament in Recital 88. For this reason, **the Regulation should safeguard the interests of patients in medical research.** The course of research is constantly affected by novel therapeutic opportunities. Yet future research still relies on extensive collections of data and samples collected over long stretches of time. Future research purposes are often impossible to predict. A legal requirement for patients to reconsent often for novel forms of research is therefore encumbering for both the researcher and the patients.

As illustrated below, continuous reconsenting will often be burdensome for patients. So-called consent fatigue would eventually even hamper their active research participation, which would severely limit the availability of specimens and follow-up data to biobanking focused on severe diseases like cancer. Eventually, this would thwart progress in research and the potential for innovation. While protecting the data from misuse and illegal disclosure, the Regulation should also ensure that samples and data do not go to waste. **Patients should therefore have a right to consent to the inclusion of their data and biomaterials to biobanks and databases for biomedical research**, even if potential research objectives cannot be stated as specifically as in a concrete clinical study. In our understanding, the underlying message of Recital 25aa (Council version) fits this general form of consent.

Example: Luca, the ordinary cancer patient

At just 22 years of age, Luca has just been diagnosed with malignant melanoma – cancer of the skin. His doctor transfers him to a Comprehensive Cancer Center associated with a research unit. The Center assures Luca that he will be offered the best therapy for his type of melanoma available today, a targeted therapy for his particular type of cancer.

Such novel approaches, which often are referred to as forms of Precision or Personalised Medicine, are developed through the generosity of thousands of cancer patients participating in and providing tissue and medical and genetic data to biomedical research. Genetics is particularly crucial to cancer research, since all cancers arise due to alterations in DNA. While some cancer-causing mutations are heritable and confer an elevated risk of developing cancer, others occur over the course of a person's lifetime in individual cells. Current state-of-the-art methods used in identifying the genetic backgrounds of cancer differ from those in classical biomedical studies. Instead of focusing on specific hypotheses, new methods involve computer-led searches of statistical patterns. Such methods require as much high-quality data as possible, collected over long time-frames and analysed time and again using algorithms which are repeatedly updated and improved on. These databases cannot be operated on the basis of consent for specific studies: it would be impossible to obtain consent from each and every patient who contributed for every single exploration of the collected data. But many patients have been happy to consent to the use of their tissue and data for future biomedical research as such after having been informed about the access policies and other

safeguards, as well as remaining privacy risks, which will of course never be zero – even as researchers do their utmost to deserve the ongoing trust of these contributors.

Just like many patients before him, Luca will not just receive life-saving or at least life-prolonging therapy. He will likely also be asked to contribute tissue and his data for future cancer research, including research into other aspects concerning health and disease which might have an influence on the development of cancer. Nobody knows the precise directions that future cancer research involving data collected at present will take. Yet many if not most other patients across Europe are comfortable to contribute in this way to the pool of data and tissue available to research, thus helping improve and innovate treatment opportunities for future generations.

After one year of therapy and intensive medical care, Luca tries to carry on with his normal life. Like many others, he is willing to support research through the tissue and data he provided. Beyond regular health follow-ups, however, he would prefer not to be reminded of a very difficult time in his life.

2. Maintain the Distinction Between Processing of Personal Data for Scientific Research Purposes and Other Forms of Processing

Concrete proposals

We approve of the amendments to Recital 126 (Parliamentary amendments and Council version), aimed at distinguishing processing of data in research from other forms of processing.

We are concerned that the term 'high public interest' related to the processing of sensitive data in Parliamentary amendments for Recital 123a and Article 81(2a) (a.o.) may lead to the politicization of research and urge a change to 'public interest'.

We are concerned that amendments to Articles 81(2a) and 83(1b) (Parliament version), stating that data processing involve pseudonymisation 'under the highest technical standards', will prove severely detrimental to research and urge a wording such as 'reasonably high' standards.

We believe special provisions for processing personal data concerning health in research are best introduced in Articles 9 and 83 and urge scrapping the separate provisions as envisaged by the European Parliament in Article 81 (1b, 1c, 2, 2a).

We consider some of the derogations for processing data for scientific research purposes as envisaged by the Council in Article 83 to be more far reaching than strictly necessary. In particular, a derogation for Article 19 could be omitted.

Explanation

Biomedical research aims at furthering our knowledge of human health and developing new treatments and therapies to counter disease. For this reason, **all biomedical research can be considered a substantive public interest**. Ensuring that this remains so requires drawing a line between processing for scientific research purposes and processing for other purposes, such as direct marketing and personal profiling of clients, as follows from Parliament's and Council's amendments to Recital 126.

Historical, statistical and scientific research delivers benefits to society using personal data and currently protects privacy through various ethical, governance and technical safeguards. Many regulations relevant to biobanking touch on issues of data security, such as the WMA Helsinki Declaration of 2013, the Oviedo Convention of 1997 and protocols and OECD Guidelines on Human Biobanks and Genetic Research Databases of 2009, and even of official standards for IT quality management, laboratory competence and risk management. The Regulation should highlight the importance of such safeguards to protect data subjects. Moreover, in order to identify who may benefit from the exemptions laid down for processing for scientific research purposes, it is important to define scientific research for the purpose of the Regulation. Many commercial actors in particular may state 'research' as their goal while ignoring specific regulations such as the ones referred to above. We believe that the exemptions for scientific research should only apply to research in the public interest, and that the general rules of the data protection regulation should apply to any measures in the interest of the data subject arising from such processing. We believe the amendments to Recitals 125 and 126 put forward by the Council are useful in this regard.

A number of parliamentary amendments go one step further, raising the barriers for research too high. For one, there is a real risk that the novel designation of a need for a 'high public interest' in research while processing sensitive data (in Recital 123a, Article 9 (2g) and Article 81 (2a) (Parliament version)) will lead to an unwarranted politicization of research within the data protection governance regime. The prioritisation of public interests suggested here, a process ordinarily conducted in the dynamic interplay between science, policy and society, should have no bearing on data processing provisions. We also fear that the wording in amendments to Articles 81(2a) and 83(1b) proposed by the European Parliament, stating that data processing involve pseudonymisation 'under the highest technical standards', will prove severely detrimental to research. Instead, we urge a wording such as 'reasonably high' standards. Similarly, according to Article 81(2a) (Parliament version), research using non-anonymous health data would only be allowed if that research 'cannot possibly be carried out otherwise'. We urge you to replace 'possibly' with 'reasonably'.

Finally, we should note that **a number of novel data subject rights proposed in the GDPR are already routinely offered in research, such as the right to objec**t in Article 19 or the right to withdraw consent in Article 7, paragraph 3. It may therefore not be necessary to fully exempt researchers from the obligations under Article 19 through Article 83, as proposed by the Council.

Example: Lena, an elderly person with several common diseases.

Lena is 75 years old. She suffers from a moderate form of diabetes, high blood pressure and high cholesterol levels and has had several minor strokes and a heart attack. These have significantly lowered her general condition, but she is still able to manage her everyday life with a little help from family and friends. She is well aware that there is a strong hereditary factor for her diagnoses. As she has three children and nine grandchildren, she worries about the future health of her family. This motivated her strongly to join several research projects running at the hospital she belongs to. Even though she probably won't benefit from such research herself, she is convinced that her children and grandchildren will. So far, she participated in several studies on diabetes, stroke and even a study focusing on elderly patients suffering from multiple diseases simultaneously. Some of these studies are conducted locally at the hospital, while others are part of larger, even international research efforts. As of now, Lena has been asked to consent to every individual research project. Lena is interested in following research progress and to discuss this with the doctors and nurses involved, but she does not see it is a necessity that she explicitly consent to allowing her health data and samples to be used in further research projects in the future. She belongs to the vast majority of Swedish patients that are keen to take part in research studies: only 0,5 – 0,7 per mille of patients have chosen not allow their samples and data to be used in research.[5] As long as the research is conducted by respectable researchers and monitored by ethical review boards, Lena is confident that her data and samples will be treated in a respectful and ethical manner. She is more than happy to contribute to the development of new therapies wherever she can.

[5] See f.i. Johnsson, L.,et al, Patients' refusal to consent to storage and use of samples in Swedish biobanks: cross sectional study, BMJ 2008;337.

3. Harmonised Rules Are Preferable to Promote Pan-European Research

Concrete proposal

We appreciate the opportunity for associations and other bodies representing categories of controllers or processors to draw up codes of conduct (Art. 38) and envisage a future role for BBMRI-ERIC in this process. However, European organisations such as BBMRI-ERIC should also have the right to submit codes of conduct directly for approval to the EU Data Protection Board. Article 38 para 2 should therefore be amended as follows: 'ERICS and other European research networks or organisations representing more than three Member States shall submit the draft code of conduct directly to the European Data Protection Board.'

Explanation

Consistent harmonised rules for research at EU level are needed to promote research collaboration Europe-wide. Harmonised rules would be extremely valuable to perform pan-European research. Many collaborative research projects funded through EU Framework Programmes and Horizon 2020 suffer from fragmented and unclear data protection frameworks which make it burdensome, costly and sometimes even nearly impossible to set up common ethical and governance frameworks for the protection or privacy. Harmonised data protection rules for research which take the perspective of pan-European research into account is urgently needed, particularly in rare disease research where amassing sufficient patients is only possible through collaborative cross-border research. Disproportionate amounts of red tape will severely hinder collaborations in an area, which is already suffering from numerous practical and organizational hurdles, as they have done in the past.[6]

The opportunity to develop sector-specific rules under the aegis of the GDPR is one way of furthering harmonisation. We appreciate the opportunity for associations and other bodies representing categories of controllers or processors to draw up Codes of Conduct (Article 38). European collaboration should be encouraged and the approval procedure must support those efforts. We envisage a role for BBMRI-ERIC in the development of a European Code of Conduct for biobanking. Currently, however, Article 38 para 1a in conjunction with Article 38 para 2 leading to Article 51 para 1 only allows European research organisations to submit Codes of Conduct to national authorities. Yet given the ambitions of the European Union to strengthen the development of a European Research Area, **pan-European organisations should also have a right to submit Codes of Conduct directly to the EU Data Protection Board.** In our view it makes much more sense to have organisations such as BBMRI-ERIC submit Codes of Conduct developed for European research after Europe-wide consultations, negotiating sector-specific compromises that take various national approaches into account to a European data protection supervising authority, rather than to one or even multiple national authorities which are once again likely to read such Codes through a Member State-specific lens.

[6] See for example Hansson MG, Gattorno M, Stjernschantz Forsberg J, Feltelius N, Martini A, Ruperto N, Ethics bureaucracy – A significant hurdle for collaborative follow-up of drug effectiveness in rare childhood diseases, *Archives of Diseases in Childhood* 2012. doi:10.1136/archdischild-2011-301175.

Example: shared data protection frameworks for European research consortiums[7]

In practice, it is extremely difficult within a collaborative multi-partner project to set up data protection frameworks acceptable to all partners. Many research projects involve sharing medical data (most often collected several years ago to conduct clinical trials) between consortium members in order to discover scientific knowledge that cannot be detected in an isolated data set. Reusing and sharing such data raises many questions. Can clinical data sets be reused for the purpose of projects in the framework of the Innovative Medicines Initiative (IMI), Europe's largest public-private partnership between the European Union and the European pharmaceutical industry? When new consent cannot be collected from all patients involved in the studies, does clinical data need to be fully anonymized before reuse? If so, what technical and legal requirements are involved? Is authorization from the data protection authority mandatory? What is the applicable law? Who is the data controller? Many such issues were encountered in projects such as European research projects Electronic Health Records for Clinical Research (EHR4CR), eTRIKS, Predict-TB, P-medicine, CEO roundtable on Cancer, PARENT, EMIF, SALUS, TRANSFoRm, and many others.

It soon became clear that it is extremely difficult to reach an agreement in a multi-country collaborative project on the requirements to comply with all applicable data protection regulations. It therefore seemed more fruitful to merge efforts and develop a common Code of Practice covering all areas of uncertainty related to secondary use of medical information. The Code of Practice on Secondary Use of Medical Data in Scientific Research Projects aims to establish a set of rules governing the secondary use of medical data in biomedical research in a most clear manner. The Code is intended to allow researchers who are not specialists in data protection law to understand the basic legal requirements and to comply with them. It has been designed as a minimum standard in order to assure researchers that they act in compliance with fundamental legal requirements as long as they follow the Code. However, researchers and research entities may establish a more stringent level of data protection if this is required by their research content or by local laws. Especially with regard to the ongoing technical developments, a permanent scrutiny of the privacy enhancing safeguards has to take place.

The Code is a joint effort of academic research institutes and pharmaceutical companies, supported by several directorates of the EC as well as by the clinical and health informatics research communities. The Code is now becoming recognized and used in the scientific community involved in collaborative projects in the health sector, as well as by data protection experts and European institutions. The Code was submitted to the French and Belgian Data Protection Authorities for advice. Any stakeholder and participant in healthcare research are invited to adhere to and comply with the Code as a Europe-wide approved and agreed body of rules that translates, clarifies, and complements the European legal framework in the field of patients' data security. It is a starting point to become standard soft law guidance across Europe for academic and industry research projects in the health sector.

[7] Text and example drawn from Anne Bahr and Irene Schlünder. 2015. Code of practice on secondary use of medical data in European scientific research projects. International Data Privacy Law: ipv018. Available from http://dx.doi.org/10.1093/idpl/ipv018.

4. Member State-Specific Derogations for Processing Personal Data for Scientific Research Purposes Remain Important

Concrete proposals

Maintain specific exemptions for processing of special categories of personal data, including genetic data and data concerning health, for purposes of scientific research in Article 9 para 2(i) (Council version) and Article 83, including Member State-specific derogations for the requirement of consent.

Make sure that Member State-specific derogations are not invoked to block, delay or otherwise unduly frustrate cross-border data exchange for research purposes. Therefore make the derogation clause consistent by introducing specific safeguards in Article 83, as indicated in Article 9 para 2 (i).

In addition, established national and international legislative frameworks, guidelines and codes of conduct relating to scientific research should be acknowledged specifically in Article 83.

Explanation

Harmonising data protection is a fundamental principle underpinning the General Data Protection Regulation. Currently, however, many Member States' research and research infrastructures are operating on the basis of specific derogations and interpretations of the Data Protection Directive. Many of these differences relate to the nature of national health systems, which differ markedly from State to State due to historical reasons. The underlying values and constitutional rights may be the same, but Member States balance and enact these rights considerably different from one another, resulting in different safeguards and exemptions for the many complex situations in which data is gathered and processed for scientific research. **Such derogations should not be used by Member States or competent authorities such as funding agencies and ethics committees to block cross-border research and exchange of personal data for research purposes**.

At the same time, achieving full harmonisation for health research through the General Data Protection Regulation would be too ambitious a goal. Current derogations under the Data Protection Directive provide for appropriate data protection safeguards. To abandon these abruptly in the Regulation would undermine and destroy entire areas of extremely valuable research altogether. Hence, such derogations should not be abandoned completely at this point. **The General Data Protection Regulation should leave sufficient leeway for Member State-specific approaches** in the absence of harmonised health systems. For instance, while some Member States stress the role of ethics committees in providing waivers for consent, others such as Belgium, Denmark, The Netherlands and Sweden mandate opportunities to opt out. In this regard, we urge Parliament, Council and Commission to maintain exemptions for processing of special categories of personal data in Article 9 para 2(i) (Council) and Article 83. In addition, a number of derogations for processing of data for scientific purposes should be maintained as well, particularly derogations from the requirement of (re)consenting for further processing of personal data concerning health. Ideally, established national and international legislative frameworks, guidelines and codes of conduct relating to scientific research should be acknowledged specifically in Article 83.

Example: public health registries and their need for wide coverage[8]

Disease registries provide hugely important resources to public health research. For instance, population-based registries are vital to multiple forms of cancer research, such as linking incidences of cancer data to environmental exposure, evaluation of population-level screening programmes, survivorship studies as well as prognostics. Although safeguards such as Trusted Third Parties (TTP) and Privacy Enhancing Technologies (PET) are common for registry-based research, such research often needs to be performed with data collected for purposes other than research. Assessing disease risks relating to things such as substance exposure (e.g. asbestos) or technology (e.g. mobile phones) require data on very large populations collected over several decades. Such risks cannot be properly assessed without repeated linkage and direct checks of source data (such as electronic health care records), which will often need to involve processing directly or indirectly indentifiable data.

Future uses of registry data are both plentiful and unpredictable. Who would have predicted concerns over the long-term effects of mobile phone use even twenty years ago? In general, health data should therefore be available for further processing for scientific research purposes. Solid experience with registry-based public health research throughout Europe, particularly in the Nordic countries, demonstrates that it is possible to unite protection of personal data while also ensuring access to data for research purposes for the benefit of public health. Data protection rules on the Member State-level are complex and nuanced also with regard to public health research. Ethical and legal rules at Member State or regional level offers data subjects a guarantee that the use and reuse of their data for research purposes is in line with societal values at any given point in time.

Example: pathology archives, residual use and opt-out systems

Retrospective studies relying on excised tissue collected routinely in the course of cancer care regularly lead to the restructuring of diagnostic procedures, resulting in dramatically improved treatment strategies for many forms of cancer. Retrospective use of tissue samples from pathology archives is often the only way to do such research, particularly for follow-up studies stretching out over decades. Consent provided decades ago could hardly have anticipated the emergence of current state-of-the-art molecular techniques, and the same will likely hold for tomorrow's analytical tools.

Such situations are dealt with differently from Member State to Member State. In The Netherlands, storage and use for scientific research of tissue excised in the context of treatment is covered by data protection and medical treatment legislation which stipulates that further processing for research purposes is allowed, provided that tissue and data are sufficiently anonymised and patients and donors are provided with the opportunity to opt out of such use. These clauses are undergirded by professional codes of conduct which spell out further safeguards, for instance by having researchers apply to ethics commissions for approval and by stressing the need to inform all patients about the opportunity to opt out of research. Survey research and in-depth interviews with patients show that most patients see opting out as a good way of balancing the rights and interests of current and future patients.

[8] Text and example drawn from EUROCOURSE position paper on the General Data Protection Regulation: http://ieaweb.org/wp-content/uploads/2012/12/2012-10-5-ENCR-EUROCOURSE-Position-paper-on-the-proposed-EU-Data-Protection-Regulation.pdf.

BBMRI-ERIC

The **Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC)** shall establish, operate and develop a pan-European distributed research infrastructure of biobanks and biomolecular resources in order to facilitate the access to resources as well as facilities and to support high quality biomolecular and medical research. BBMRI-ERIC is designed to facilitate the joint establishment and operation of research infrastructures of European interest and beyond. The ERIC status allows pulling together biobanks and biomolecular resources into a **pan-European facility** and providing access to collections of partner biobanks and biomolecular resources, their **expertise and services on a non-economic basis**. BBMRI-ERIC is established **for an unlimited period of time**. The activities of BBMRI-ERIC shall be politically neutral and guided by the following values: pan-European in scope, combined with scientific excellence, transparency, openness, responsiveness, ethical awareness, legal compliance and human values.

BBMRI-ERIC consists of **17 Member States and one International Organisation. It is distributed by nature and builds on the National Nodes** that coordinate the respecitive national biobanks and biomolecular resources, and links its activities with the pan-European activities of BBMRI-ERIC. This makes BBMRI-ERIC one of the largest research infrastructures for health research in Europe.

Members: Kingdom of Belgium, Czech Republic, Federal Republic of Germany, Republic of Estonia, Hellenic Republic, French Republic, Italian Republic, Republic of Malta, Kingdom of the Netherlands, Republic of Austria, Republic of Finland, Kingdom of Sweden, United Kingdom of Great Britain and Northern Ireland

Observers: Kingdom of Norway, Republic of Poland, Swiss Confederation, Republic of Turkey, Internatinal Agency for Research on Cancer (IARC/WHO)

Common Service ELSI: In general, Common Services shall consist of the facilities of BBMRI-ERIC that provide expertise, services and tools relevant for the pursuance of BBMRI-ERIC's tasks and activities, laid down in the Work Programme. (Statutes, Article 15.1) The Common Service ELSI aims to facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices.

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