



Alternative Rule-Making within European Bioethics – Necessary and Therefore Legitimate?

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Abstract

There are two core principles in the law and ethics of biomedical research that could be considered universally accepted: first, all handling of personal data and human biological samples is conditioned by the informed consent of the individual involved; second, all medical research on human biological samples and personal data should be placed under the review of research ethics committees. These concepts are included in international, regional and national guidelines, rules and regulations for processing of data and biobanking. However, the legal implementations are carried out within each national legal order, by national organs enacting administrative decisions applicable within the state. In order for the research project to function in a multinational setting, the EU has developed soft law tools and governance mechanisms to facilitate European biomedical research. The question is whether this can be considered valuable and legitimate on the grounds of enhancing conditions for medical research.

Keywords

bioethics – human rights – soft law – legislative competences

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1 Introduction

There are two core principles in the law and ethics of biomedical research: (1) the need for informed consent and (2) ethical approval to allow a safe and legitimate handling of biological samples and data within research.¹ These principles aim at safeguarding the right to autonomy, dignity and privacy for patients, research and data subjects, as laid down in international and European human rights law.² Traditionally, the legal implementations of these core principles are carried out within each national legal order where biomedical research is conducted by national authorities enacting administrative decisions applicable within the state. The point of departure is that all research conducted within a state must be reviewed by a research ethics committee within that same state.³ The question of legislative competences in regulating cross-border medical research is thus essential. The EU can regulate the processing of data, but not the medical research or the handling of human biological samples as such. Notwithstanding, the EU is an important actor in the research field. The EU has introduced the European Research Area (ERA), which has a substantial research funding budget and can establish research infrastructures for European researchers. The research funded by the EU is found in a diverse and scattered administrative legal landscape with few official cross-border tools, which can in itself be considered an obstacle for research.⁴ In this article the work within the BBMRI-ERIC, one of the first research infrastructures to be set up by the

1 Matthias Ruffert and Sebastian Steinecke, *The Global Administrative Law of Science* (Springer 2011) 94–96. See further section 2.

2 At the international level, see Article 1 of the Universal Declaration of Human Rights (UDHR), Article 7 of the International Covenant on Civil and Political Rights (ICCPR) and Article 6 of the UNESCO Universal Declaration on Bioethics and Human Rights. At the European level, see Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, Article 5–9, 10 of the Convention on Human Rights and Medicine and Articles 3, 7 and 8 of the European Union Charter of Fundamental Rights. See further section 2.

3 It has traditionally been held that the task of handling administrative issues concerning the state, its citizens and activities carried out within the state borders lies within the competence of each sovereign state, see Henrik Wenander, 'A toolbox for administrative law cooperation beyond the state' in Anna-Sara Lind and Jane Reichel (eds.), *Administrative Law Beyond the State – a Nordic Perspective* (Liber Martinus Nijhoff Publishers 2013) 49, with further reference to Jürgen Schwarze, *European Administrative Law* (revised 1st edn, Sweet & Maxwell 2006).

4 Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research, *Biobanks for Europe: A challenge for Governance*, Directorate-General for Research and Innovation Science in society, European Commission, EUR 25302 EN (2012).

EU, will be analyzed. The BBMRI-ERIC aims to facilitate cross-border medical research, not the least with regard to overcoming administrative difficulties. Since the BBMRI-ERIC does not have any competence to enact legally binding acts, soft law is the only tool available.

The main question here is whether the use of soft law tools for informed consent and ethical approval in the area of cross-border procedures can be considered valuable and legitimate. Scharpf distinguishes two ways to achieve legitimacy in rule-making, i.e. in-put legitimacy and out-put legitimacy.⁵ In a classic nation state setting, legitimacy can be derived through the process of enacting rules (in-put legitimacy), for example, through the direct or indirect participation of a democratically elected parliament.⁶ Within the concept of a democratic state lies an understanding that government officials ultimately must derive their power from citizen-based elections, that public powers is exercised in accordance with the rule of law and is restricted through a guaranteed possibility of change of power.⁷ Hereby, citizens are able to hold public rule-makers accountable, directly or indirectly. On the other hand, in cases where there is a need for common solutions on cross-border problems, Scharpf holds that regulations answering to the very needs of society can be appreciated as legitimate on the out-put side: the absence of political accountability can to a certain extent be redressed by the effectiveness in achieving consensual goals; the emphasis on goals being consensual in themselves then counts for an important restraint on possible objects of regulation.⁸

Standard-setting activities within the international research community have long traditions, especially regarding technical aspects of procedures and protocols, such as methods for handling samples, freezing, etc.⁹ In regard to procedures for informed consent and ethical approval, however, relying solely on out-put legitimacy may be more questionable. The practice of informed consent and the involvement of research ethics committees are measures that allow the state to monitor the upholding of human rights, as set out in

5 Fritz W. Scharpf, *Governing in Europe: Effective and Democratic?* (OUP 1999) 7–13.

6 Ibid 7.

7 Armin von Bogdandy, 'Globalization and Europe, How to Square Democracy, Globalization and International Law' (2004) 15 EJIL 889.

8 Scharpf (n 5) 22–23.

9 See for example OECD Consensus Documents, Safety Assessments of Transgenic Organizations, 2010. Also the EU has enacted legislation on this type of matters; Directive 2002/98/EC, of the European Parliament and of the Council of 27 January 2003 Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components and Amending Directive 2001/83/EC, 2001 O.J. (L. 33).

international and European human rights law. BBMRI-ERIC seems to have the ambition not only to set standards for informed consent and ethical approval, but also to conduct the assessment of research itself. Could this task be upheld by an organization beyond the state with only a weak connection to the democratically elected national parliaments? Could the value of the potential out-put legitimacy of the rule-making, namely: better health, sufficiently compensate the lack of democratic law-making?

2 Bioethics as Fundamental Rights

As set out above, two basic points of departure can be identified in national and international law concerning the handling of human biological samples in research. First, the use of human biological samples in research is conditioned on the informed consent in some form of the donor. Second, research on human biological samples should be placed under the review of independent research ethics committees.¹⁰ Even though only a few binding international conventions directly address these issues, some general international conventions¹¹ as well as soft law documents can be relevant in this context too.¹² The EU Charter of Fundamental Rights (the EU Charter) states for example in Article 3.2.a that

10 Matthias Ruffert and Sebastian Steinecke, *The Global Administrative Law of Science* (Springer 2011) 94–96.

11 At the international level, the UN has enacted the International Covenant on Civil and Political Rights (ICCPR) 1966, which targets medical or scientific experimentation, but probably not research on samples of biological material in a biobank, see the General Comment No. 20 Replaces General Comment 7 concerning prohibition of torture and cruel treatment or punishment (Art. 7) (Mar. 10, 1992). In Europe, the Council of Europe has several documents; European Convention for the Protection of Human Rights and Fundamental Freedoms (1950), the Social Charter (1961, revised and expanded in 1996), the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data Council of Europe (1980), the Council of Europe Convention on Human Rights and Biomedicine and its Additional protocol concerning Biomedical Research.

12 See for example Council for Int'l Organizations of Med. Sciences & WHO, International Ethical Guidelines for Epidemiological Studies, guideline 2 (2002), Council for Int'l Organizations of Med. Sciences & WHO, International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects (2008), UN Guidelines concerning computerized data files (1990), Council of Europe Recommendation Research on Biological Material of Human Origin (2006), and OECD Guidelines governing the Protection of Privacy and Transborder Flows of Personal Data (2013). There is also ongoing work within, for example, the Global Alliance for Genomics and Health, available at <http://genomicsandhealth.org/node/12703>. See further Elisabeth Rynning, 'Legal Challenges and

in the fields of medicine and biology the free and informed consent of the person concerned, according to the procedures laid down by law, must be respected. Informed consent is also recognized as one of the grounds that render the processing of personal data lawful.¹³ There is a strong consensus that medical research on human biological samples must be approved by a research ethics committee.¹⁴ A direct consensus regarding the role of research ethic committees in connection to data protection does not seem to exist. Nevertheless, EU law requires that the Member States are to allow the processing of sensitive data in research only when 'suitable safeguards' are in place.¹⁵ A suitable safeguard could often be the involvement of a research ethics committee, what for example is seen in Swedish law.¹⁶ As will be seen further on, ethical review by a committee is often a requirement to attain research grants even without the handling of human biological samples.¹⁷ Research ethics committees thus play a very central role in the process of launching medical research projects, without which the research cannot be conducted.¹⁸

Strategies in the Regulation of Research Biobanking' in Jan Helge Solbakk, Søren Holm and Bjørn Hofmann (eds.), *The Ethics of Research Biobanking* (Springer 2009).

- 13 Article 8.2 of the EU Charter, OECD Guidelines governing the Protection of Privacy and Transborder Flows of Personal Data (2013), [C(80)58/FINAL, as amended on 11 July 2013 by C(2013)79] and Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (1980).
- 14 Several guidelines explicitly require the involvement of such committees, for example Article 23 of the World Medical Association's Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects and Guideline 2 of the Council for Int'l Organizations of Med. Sciences & WHO, International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), See also Eleni Zika et al., *Biobanks in Europe: Prospects for Harmonisation and Networking*, JRC Scientific and Technological Reports (European Commission 2010).
- 15 Articles 8 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Article 89 in the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (In the following: General Data Protection Regulation 2016/679.), enacted on May 24, 2016 and to be applied from May 24, 2018.
- 16 See for example in Swedish law, section 19 *Personuppgiftslag* (1998:204) [Personal Data Act, implementing the EU data Protection Directive], which refers to lag (2003:460) *om etikprövning av forskning som avser människor* [Act concerning the Ethical Review of Research Involving Humans].
- 17 See section 3.2.
- 18 The role and function of the ethic review committees in cross-border biobanking have been discussed vividly, see for example Jane Kaye, 'From single biobanks to international

An important function of the ethics committees is to connect the international principles to the local law and praxis.¹⁹ Research ethics committees at the national level are thus considered as a strong legitimizing measure for protecting human rights within bioethics. The competence and functioning of the committees do vary from one country to another, though, hence contributing to the diverse and scattered legal landscape of European law on biomedical research. In the following section, EU legislative competences that introduce a workable administrative structure for research ethics and bioethics will be analyzed.

3 EU Competences within Research and Bioethics

Key to understanding the regulatory choices within the EU research governance lies in the division of legislative powers between the EU and its Member States following the principle of conferred powers, and in the interpretation of the legal basis within the Treaties that empower the EU to enact specific legal acts. Section 3.1 discusses the basic constitutional principle of conferral. Section 3.2 maps out the competences and activities within the field of medical research and bioethics. Section 3.3 presents the functions and aims of the BBMRI-ERIC are presented, with a special focus on its work within bioethics.

3.1 *The Principle of Conferral*

It follows from the principle of conferral as laid down in Article 5.2 of the Treaty of the European Union (TEU) that the EU can only exercise the legislative powers the Member States has conferred upon it. Traditionally, the EU could only legislate on matters that were related to the establishment of an internal market with a free flow of goods, workers, services and capital. Over the years, the EU has also gained legislative power in other domains, for example

networks: developing e-governance' (2012) 130 *Human Genetics* 377; Edward S. Dove, Bartha M Knoppers and Ma'n H Zawati, 'Towards an ethics safe harbor for global biomedical research' (2014) *Journal of Law and the Biosciences* 3 and Jean V. McHale, 'Accountability, Governance and Biobanks: The Ethics and Governance Committee as Guardian or as Toothless Tiger?' (2011) 19 *Health Care Analysis* 231.

19 Article 23 of the Helsinki Declaration holds 'It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration'.

with regard to public health, data protection and research.²⁰ When it comes to bioethical issues, the EU does not have an independent competence to enact legal acts.²¹ However, when the EU is competent to legislate on a different ground, such as the internal market or the promotion of public health, the EU may refer to ethical frameworks at both international and national level in its legislation, hence presupposing the application of ethical principles in the implementation of the concerned EU act. This is the case in a Directive on *in vitro* diagnostic medical devices²² and the recently enacted Clinical Trial Regulation.²³ By broadly interpreting the treaty provisions that foresee in a legal basis for the EU to adopt rules in substantive policy areas, complementary rules of administrative, supervisory or, in this case, ethical content that is needed in order for the proper functioning of the substantive rules are read into these treaty provisions.²⁴

In regard to medical research without a connection to the internal market or another area where the EU is competent to act, the gateway to EU law-making competence is however not available. National law then prevails. However, with respect to research, the EU may also use other means than enacting legislation for the harmonization of the legal orders of the Member States, as will be discussed below. The EU has several governance tools that can be considered quite effective, especially the programmes for funding of research projects and the introduction of the international organizations for research infrastructure consortia referred to as 'ERICs'. The latter provides a platform for researchers to develop standards that may be applied to research projects over time.

20 Isidora Maletic, *The Law and Policy of Harmonisation in Europe's Internal Market* (Edward Elgar 2013).

21 Helen Busby, Tamara Hervey and Alison Mohr, 'Ethical EU Law? The Influence of the European Group on Ethics in Science and New Technologies' (2008) *European Law Review* 803.

22 Article 1.4 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices. See also recital 33 of the preamble. The Directive is currently under the process of being redrafted, in the form of a Regulation, see Commission Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, COM(2012) 542 final.

23 Article 8 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use.

24 See for example case C-270/12 *United Kingdom v European Parliament and Council*, EU: C: 2014:18, the *ESMA*-case, in regards to the possibilities of the EU legislature to include delegation of powers to an agency in the competence conferred to the Union in Article 114 TFEU.

3.2 *EU Competence and Activities within the Area of Research and Bioethics*

Research has been on the EU's agenda for a long time and since the Maastricht Treaty in 1993 the EU is competent to act in this regard.²⁵ The Lisbon Treaty introduced a European Research Area. According to Article 179 of the Treaty of the Functioning of the European Union (TFEU), the EU shall have the objective of strengthening its scientific and technological bases by achieving a European Research Area, characterized by the free circulation of researchers, technological development and space. However, the general competence of the EU to act within this area is limited in several ways. Article 4.3 of TFEU states the following:

In the areas of research, technological development and space, the Union shall have competence to carry out activities, in particular to define and implement programmes; however, the exercise of that competence shall not result in Member States being prevented from exercising theirs.

The EU may thus carry out EU programmes on research, but cannot enact binding rules. Further, the principle of pre-emption - which otherwise applies when the EU has exercised its competence in areas where competence is shared with the Member States (Article 2.2 TFEU) - does not apply here. The EU measure does not prevent the Member States from acting.

3.2.1 General Competences

Articles 180–181 TFEU set out what actions the EU may take, namely primarily complementary and coordinated actions. In Article 182 TFEU it is stated that the EU may adopt multiannual framework programmes, setting out all the activities of the EU, including programmes for research funding. The EU plays a major role as a funder of research. One part of the 2020 strategy, in which the EU has set out several steps to follow in order to achieve a sustainable economy and growth in Europe, is directed to research and innovation.²⁶ The EU has introduced several agencies, programmes and instruments to facilitate research. One of them is the European Strategy Forum on Research Infrastructures

²⁵ Ruffert and Steinecke (n 1) 67.

²⁶ Communication from the Commission, Europe 2020 A strategy for smart, sustainable and inclusive growth, COM (2010) 2020 final. See further Jane Reichel, 'BBMRI-ERIC – an analysis of a multi-level institutional structure in the EU and beyond' in Anna-Sara Lind and Jane Reichel (eds.), *Administrative Law beyond the State – Nordic Perspectives* (Liber Martinus Nijhoff Publishers 2013).

(ESRI), a group tasked with identifying and supporting coherent and strategic policies for research infrastructures in Europe.²⁷

Another tool available to the EU is found in Article 187 TFEU, stating that the EU may set up joint undertakings and infrastructures. BBMRI-ERIC is an example of such an infrastructure, which will be discussed further in section 3.3.

3.2.2 EU as a Research Funder

The main channels for EU funding are the Framework programmes²⁸ that make up for a great part of the EU budget; the current Horizon 2020 programme includes nearly €80 billion of funding available over 7 years.²⁹ In order to receive funding, applicants amongst others need to ensure that the research conducted is to be carried out in compliance with fundamental ethical principles. The previous framework programmes and now the Horizon 2020 programme set out specific requirements for researchers to follow in order to receive funding.³⁰ As is stated in Article 19 of Regulation 1291/2013:

All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of

27 Michaela Mayrhofer and Barbara Prainsack, 'Being a member of the club: the transnational (self-) governance of networks of biobanks' (2012) 12 *International Journal of Risk Assessment and Management* 69.

28 Initially the framework programmes were numbered up to seven but instead of an 8th programme, the current one is called Horizon 2020. The programmes last over 7 years, the currently 2014–2020. See Commission Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020 – The Framework Programme for Research and Innovation, COM/2011/0809 final.

29 See the Commission's webpage <http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020> and Ruffert and Steinecke (n 1) 69.

30 Article 19 Regulation 1291/2013 of the European Parliament and of the Council establishing Horizon 2020 – The Framework Programme for Research and Innovation (2014–2020). Regarding earlier framework programmes, see Decision 1982/2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007–2013) [2006] O.J. L412/1. See further Busby, Hervey and Mohr (n 21) 833.

a person, the right to non-discrimination and the need to ensure high levels of human health protection.³¹

It might be interesting to note the order in which the principles are listed; the principle of proportionality first, and then the rights of privacy, data protection, integrity and so forth. According to the preamble of the EU framework decision and the Horizon 2020 Regulation, the opinions of the European Group on Ethics on Sciences and New Technologies (EGE) will be taken into account.³² The importance of promoting practices of ethical governance was further underlined in a Commission report from the Expert Group on Global Governance of Science.³³ This means that all research projects funded by the EU will have to adhere to a European layer of ethics in addition to the national ethics regulation, applied by the national research ethics committees.

3.2.3 Research Funding and Policy-making

Another strand of EU activity in the area is the support and funding of researchers in specific projects, aiming to identify governance problems, enacting standards and guidelines, etc. The Commission has thus commissioned expert groups to write reports on the complexities of the legal landscape and governance structures for biobanking³⁴ within the EU.³⁵ The Commission also funds several projects that aim at developing standards and tools for medical research and biobanking. Via the Innovative Medicines Initiative (IMI),³⁶ the Commission has funded a private-public venture to adopt ethical standards for the use of electronic health records in clinical trial.³⁷ Within another EU-funded project – the hSERN.eu –, a comprehensive set of ethical standards for

31 Ibid Article 19.

32 Recital 33 of the preamble to the Decision 1982/2006 and recital 29 of the preamble to the Horizon 2020 Regulation. See further Aurora Plomer, 'The European Group on Ethics: Law, Politics and Limits of Moral Integration in Europe' (2008) 14(6) *European Law Journal* 839, 847.

33 Global Governance of Science, Report of the Expert Group on Global Governance of Science to the Science, Economy and Society Directorate, Directorate-General for Research (European Commission 2009) 9.

34 The terms refer to research conducted on biobanks.

35 Zika and others (n 14) and Biobanks for Europe. A Challenge for Governance, Report of the Expert Group with Ethical and Regulatory Challenges of International Biobank Research, Directorate-General for Research and Innovation (European Commission 2012).

36 Available at <<http://www.imi.europa.eu>> accessed 17 June 2016.

37 EHR4CR-project <<http://www.ehr4cr.eu>> accessed 17 June 2016.

human samples exchange has been developed.³⁸ In the B3Africa-project, one of the tasks objectives is to develop a legal and ethical framework for sharing data between Africa and the EU.³⁹ Other projects that may be mentioned in this regard are BioMedBridges,⁴⁰ BioSHaRE,⁴¹ BBMRI-LPC,⁴² and MeDALL.⁴³ In yet another project – the EUCellEx project –, the purpose is rather to influence the content of EU legislation within the field of medical research, namely cell based regenerative medicines. According to the project homepage, the aim is to examine:

[T]he application of the European rules regarding cell banks together with current practices in respect of the therapeutic use of human cells in the different countries [in order] to submit the data obtained to the European Commission for it to draw up legislative measures in line with medical advances in this field.⁴⁴

3.3 *BBMRI-ERIC as a Cross-border Governance Tool for Research*

Another side of EU activities in the field of research is the setting up of international organizations for research infrastructures, called European Research Infrastructure Consortium (ERIC). Article 187 TFEU mandates the EU to ‘set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration’. The procedure for establishing an ERIC follows a regulation enacted in 2009, the ERIC Regulation.⁴⁵

3.3.1 The ERIC Regulation

According to the ERIC Regulation, all ERICs are international organizations. The setting-up and internal functioning of an ERIC shall be governed by EU

38 Available at < <http://www.hSERN.eu> > accessed 17 June 2016.

39 Available at < b3Africa.eu > accessed 21 June 2016. The author is part of this project.

40 Available at < <http://www.biomedbridges.eu> > accessed 17 June 2016.

41 Available at < <https://www.bioshare.eu> > accessed 17 June 2016.

42 Available at < <http://www.bbmri-lpc.org> > accessed 17 June 2016.

43 Available at < <http://medall-fp7.eu/> > accessed 17 June 2016. Further examples of initiatives and projects that are funded by the Commission can be found in the above-mentioned report, Biobanks for Europe. A Challenge for Governance, Report of the Expert Group with Ethical and Regulatory Challenges of International Biobank Research, Directorate-General for Research and Innovation (European Commission 2012) 20–21.

44 Available at < <https://www.eucellex.eu> > accessed 17 June 2016.

45 Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC).

law, in particular the ERIC regulation; by the Commission's decision to establish an ERIC; by the law of the State where the ERIC has its statutory seat and lastly, by the statutes of the ERIC and their implementing rules.⁴⁶ The Commission may decide to establish an ERIC at the request of at least three Member States, thereby providing a platform for the Member States to jointly fund and operate research facilities. The initiative to establish an ERIC comes from the Member States, but the idea may very well be routed within EU research policies. This was the case with the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), which was one of the first projects to enter the European Research Infrastructure's preparatory phase of the ESFRI roadmap, funded by the Commission.⁴⁷

The law applicable to the activities carried out by the ERIC will firstly be the law of the country where the ERIC has its seat, or, when activities are carried out in other states, according to the law of this state. This issue is not clearly laid down in the ERIC regulation itself, but in recital 21 of the Preamble it is stated that if the ERIC has a place of operation in another state, the law of that latter state should apply in respect of specific matters defined by the statutes of the ERIC.⁴⁸ The connection between the ERIC and the EU is however strong. It is the Commission who takes the decision to establish the ERIC and the Commission must approve of amendments of core parts of the statutes of the ERIC.⁴⁹ The ERIC must further report to the Commission and to the relevant public authorities, which, even if it is not stated explicitly, presumably refers to the competent authorities in the Member States, on a yearly basis.⁵⁰ The Commission thus supervises the ERICs, not merely on grounds of financial issues, but also on the substantive work of the ERIC. According to Article 17.3–5 of the ERIC Regulation, the supervision is carried out to on the basis of 'the ERIC Regulation, the decisions adopted on the basis thereof or other applicable law'. The Commission may, on the suspicion of a serious breach of these legal sources, first request explanations from the ERIC and/or its members. If the Commission concludes that an ERIC actually is in serious breach, it may suggest remedial actions and, as a final resort, the Commission may repeal its decision of establishing the ERIC.

46 Article 7 and 15 Council regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC).

47 ESFRI Roadmap for Research Infrastructures, Update 2008, and BBMRI.eu.

48 Jane Reichel, Anna-Sara Lind, Mats G. Hansson and Jan-Eric Litton, 'ERIC – A new governance tool for Biobanking' (2014) 22 *European Journal of Human Genetics* 1055.

49 Article 6 and 11 Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC).

50 Article 17.1 Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC).

3.3.2 The BBMRI-ERIC

The BBMRI-ERIC was established in December 2013, with its seat in Graz, Austria. According to Article 3 of its statutes, the aim of BBMRI-ERIC is to facilitate the access to resources as well as facilities and to support high-quality biomolecular and medical research.⁵¹ As of now, the BBMRI-ERIC does not run any biobanks of its own, but these are located within the national nodes. These may be either research biobanks or clinical biobanks connected to hospitals that can also be used for research. These biobanks are thus governed under the national legislation of the state where they are situated, and any use of a service provided by the biobank must be in accordance with national law.⁵²

On its website, the mission of BBMRI-ERIC is said to be to:

increase efficacy and excellence of European bio-medical research by facilitating access to the Union's quality-defined human health/disease-relevant biological resourced through associated data in an efficient and ethically and legally compliant manner.⁵³

It seeks to do so amongst other ways by 'reducing the fragmentation of the bio-medical research landscape through harmonization of procedures, implementation of common standards and fostering high-level collaboration'.⁵⁴ In order to accomplish this, the BBMRI-ERIC will conduct three common services:⁵⁵ one common biobanking and resource service, providing procedures and standards for different types of population-based, clinical-oriented biobanks and biomolecular resources; one common information technology (IT) service, coordinating and implementing the interoperability of the existing and new biological databases of biobanks; and lastly, a unit providing services within ethical, legal and societal issues (ELSI) that supports and supervises ethical and legal compliance within the activities of the ERIC.⁵⁶ One of the main tasks of the third common service, the ELSI-CS, will be to develop standards and tools to support cross-border research. Again, with no competence to enact binding rules, the ELSI-CS can merely provide soft law instruments with no

51 Article 3 of the Statutes for the Biobanking and Biomolecular Resources Research Infrastructure European Research Infrastructure (BBMRI-ERIC), available at <http://bbmri-eric.eu/>.

52 Article 1.8 and 3.3 of the BBMRI-Statutes and Reichel, Lind, Hansson, Litton (n 48) 2.

53 Available at <<http://www.bbmri-eric.eu/web/guest/21>> accessed 17 June 2016.

54 Ibid.

55 Article 3.3(e) of the BBMRI-ERIC Statutes.

56 The common services are currently being established by the BBMRI-ERIC, according to a procedure laid down in the appendix to the statutes. See further <<http://bbmri-eric.eu>> accessed 17 June 2016.

legal force within the relevant legal orders. Lastly, it may be noted that the statutes further provide for the establishment of an independent scientific and ethical advisory board, which is to evaluate the activities of the BBMRI-ERIC on a periodic basis, and makes a reference to the possibility to evaluate the ethical aspect of prospective users of the biobank-services.⁵⁷ The ELSI-CS was established in February 2015.

4 **BBMRI-ERIC and Its Common Service for Ethical, Legal and Societal Issues**

In order to provide ethical and legal compliance for all activities connected to the BBMRI-ERIC, the EU Charter and other international conventions, as well as national constitutional and administrative law is to be upheld. In Article 3.4 of the BBMRI Statutes, it is stated that:

[t]he 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.⁵⁸

The BBMRI-ERIC is not to be used to escape the regulatory and supervisory administrative structures of the Member States, but instead to guarantee that these values will be upheld. The setting up of a specific common service for ethical, legal and societal issues – an ELSI-CS –, can be seen as a means to guarantee that these principles will be an essential part of the BBMRI-ERIC. The main question in the context of this article is how the BBMRI-ERIC may influence and affect existing legal frameworks of ethic compliance within medical research, by setting their own standards for the connected researchers to abide by.

4.1 *The Establishment of the Common Service for Ethical, Legal and Societal Issues, the BBMRI-ERIC ELSI-CS*

The BBMRI-ERIC issued a call for tender for the ELSI-CS on April 2014, and, by a decision on November 2014, the joint proposal of several ELSI representatives from the national nodes of BBMRI was accepted. The ELSI-CS came into force in

⁵⁷ Article 18 of the BBMRI-ERIC Statutes.

⁵⁸ Article 3.4 of the BBMRI-ERIC Statutes.

February 2015. The common service is led by a board of directors, one director and three co-directors, an executive board of nine members and an ELSI-team consisting of 15 experts in biomedical ethics and law.⁵⁹ The tasks of the ELSI-cs is listed on its website.⁶⁰ Two of them are especially relevant for this article: first, the ELSI-cs is to organize tools and services to address ELSI issues related to biobanks and biobanking by building on already available tools and, if necessary, generating new ones; second, to provide an ethics check for research proposals submitted to BBMRI-ERIC in compliance with the BBMRI Business Plan and Statutes and with the European Commission research ethics framework. The last task refers to Article 18.2 of the BBMRI Statutes, stating that BBMRI-ERIC shall provide access to samples and related clinical data based on the scientific excellence of the proposed project as determined by an independent peer review and on ethical review of the research project proposal. The problem addressed in Article 18.2 seems to relate more to the unwillingness of researchers to share their resources than to the legal requirements for accessing samples, which also has been identified as an obstacle to efficient cross-border biobanking, alongside legal and ethical aspects.⁶¹ Article 18.2 of the Statutes continues:

Access shall respect conditions set by sample and data providers that affiliate their databases to BBMRI-ERIC. No provision in these Statutes should be understood as seeking to restrict the right of owners of Biobanks or Biomolecular Resources affiliated with BBMRI-ERIC to decide on providing access to any samples and data.⁶²

As was pointed out in a recent Workshop Report from the BBMRI-ERIC ELSI-cs, the main problem seems to be that there is resistance by institutions and individuals who fear that they will not receive recognition for their investment in building collections.⁶³

59 Available at <<http://bbmri-eric.eu/common-services>> accessed 17 June 2016.

60 Ibid.

61 BBMRI ELSI Workshop Report Sharing and access to data and human biospecimens for the benefit of patients – Towards a BBMRI-ERIC Policy, September 08–09, 2015 Paris, France. Available at <<http://bbmri-eric.eu>> accessed 17 June 2016.

62 Article 18.2 of the BBMRI-ERIC Statutes.

63 BBMRI ELSI Workshop Report. In frameworks such as the International Charter of Principles for Sharing Data and Bio-specimens, a specific section is devoted to handle issues relating to recognition and intellectual property. See Deborah Mascalconi, et al., *Ethics, law and governance of biobanking: national, European and international approaches* (Springer 2014) 1–8.

From a legal point of view, it is clear however that any access of the sample must adhere to national regulations on access and use of human biological samples and data. The purpose of adding an ethics check at the European level thus seems to aim at both satisfying ethical requirements, by upholding such a high standard that all Member States should be able to accept it, and to satisfy the interest of researchers in not having to share their samples without due regard taken to protect their interests.

4.2 *The Work of ELSI-cs*

The work of the ELSI-cs is based on a common tender by the ELSI-representatives from national BBMRI-nodes.⁶⁴ The work is described as three-dimensional: a vertical support to facilitate the activities of the national nodes, a horizontal support to coordinate initiatives on ELSI topics at EU and national level, and a transversal support to provide ethical guidance through an ethics check service for projects using the BBMRI-ERIC infrastructure. The vertical support will mainly consist of an advice function and a help desk. For example, when the Court of Justice of the European Union invalidated the Commission's decision to enter the Safe Harbor-agreement with the USA,⁶⁵ the ELSI team published a comment on the consequences of the decision on biobanking on its website.⁶⁶

The two latter dimensions of the work are of main interest here, namely the efforts that are undertaken to coordinate the work of the national nodes as regards ethical standards, etc., and the introduction of an extra European layer of ethical approval for biobankers using the BBMRI-ERIC infrastructure. An important part of the work of ELSI-cs in strengthening the ELSI issues is to regularly organize workshops and courses for the researchers in the national nodes. More specifically, the ELSI-cs will contact other EU-funded project within the area, for example those projects listed in section 3.2 (BioMedBridges, EHR4CR, BioSHaRE, EUCeLLex, MeDALL, as well as others) in order to make their achievements accessible to the research community and ensure the sustainability of useful tools. The BBMRI-ERIC is also partner to many EU

64 Proposal of tender for BBMRI-ERIC ELSI common service (ELSI-cs) in answer to the Call for proposal for tender BBMRI-ERIC common service ELSI, p. 6 (on file with the author). Main authors were Anne Cambon Thomsson (France), Mats G Hansson (Sweden), Marialuisa Lavitrano (Italy) and Jasper Bovenberg (The Netherlands). The four are today director and co-directors respectively of the ELSI-cs.

65 Case C-362/14, Maximilian Schrems mot Data Protection Commissioner, not yet published.

66 Available at <<http://bbmri-eric.eu/common-services>> accessed 17 June 2016.

funded projects, for example BBMRI-LPC and B3Africa. This corresponds to one of the basic aims of the EU for establishing ERICs in general. According to the preamble of the ERIC Regulation, the main objective in introducing the ERIC is to facilitate long-term European research projects by enabling them to function under a common legal framework.⁶⁷ Results from time-limited projects may easily be forgotten, if no long-term infrastructure can make them available. For example, the information of standards and code of conducts provided by the EU-project hSERN, for users exchanging biological samples across borders, is already today linked to the BBMRI-ERIC webpage.⁶⁸

Besides providing users with information of ethical standards, the ELSI-CS will also oversee the ethics compliance of prospective users of the biobanks connected to the BBMRI-ERIC by conducting an ethics check of their own. The check will rely on both in-house experts involved in the common services as well as an external expert panel.⁶⁹ The criteria for assessment will take into account 'European and international applicable ethical and regulatory frameworks, evidence of national framework compliance and criteria used by the EU Commission for research ethics checks and ethics review panels for coherence'.⁷⁰ The criteria will be published on the BBMRI-ERIC webpage.

Another area of activity for the BBMRI-ERIC in general and ELSI-CS in particular is engaging in policy-making at the EU level. The ELSI-CS was very active in the legislative process before the final agreement on the General Data Protection Regulation,⁷¹ a piece of legislation that is highly relevant for medical research and biobanking. Several events were held, a large number of individual meetings with parliamentarians were arranged, and a position paper was published and circulated.⁷² With the adoption of the Regulation, the BBMRI-ERIC will now direct its work towards the process laid down in Article 40 of the Regulation, enabling associations and other bodies representing categories of controllers or processors to draw up codes of conduct for processing of data.⁷³

67 Para 5 of the preamble to Council regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) and Reichel (n 26) 16.

68 Available at <<http://bbmri-eric.eu/common-services>> accessed 17 June 2016.

69 Proposal of tender for BBMRI-ERIC ELSI-CS 7.

70 Ibid, 6.

71 General Data Protection Regulation 2016/679.

72 Position Paper on GDPR (October 2015) available at <<http://bbmri-eric.eu/common-service>> accessed 20 June 2016. The work of BBMRI-ERIC was also observed by Nature, which published an article on the process: Alison Abbott, 'European medical research escapes stifling privacy laws', [16 December 2015] Nature.

73 Position Paper on GDPR 3.

The relevant part of the Article reads: ‘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.’⁷⁴ These codes of conducts are to be approved by national and European Data Protection Authorities, according to the procedure laid down in the article.⁷⁵

All in all, the *BBMRI-ERIC* and the *ELSI-CS* have quite a potential to influence the ethical work of biobank projects within the *EU*, and, with its international engagement in for example *B3Africa*, also beyond. This is achieved without a common regulatory framework enacted by the *EU* legislator, but through the infrastructures provided by the *EU* via the *ERIC* Regulation and through extensive funding from the *EU* directed to projects that can later be connected to the *BBMRI-ERIC*. By pooling the competences of bioethicists and medical law experts and by connecting former and future research projects to the infrastructure, a central platform for cross-border collaboration is built.

5 Could Fundamental Rights Legitimately Be Regulated Via Soft Law?

Referring again to Scharpf and the distinction between in-put legitimacy and out-put legitimacy,⁷⁶ it may be concluded that the work of *BBMRI-ERIC* has the potential to be legitimate from an out-put perspective, since its work responds to the needs of the biobanking community. However, the in-put legitimacy, focusing on the democratic legitimacy of actors and procedures, remains weak.

The question is whether the necessity of the tasks that the *BBMRI-ERIC* performs is enough to render it legitimate. In this regard, a further aspect needs to be taken into account: if bioethics is a fundamental right, as was suggested in section 2, this in itself should have regulatory implications.⁷⁷ Fundamental rights, and especially the limiting of such rights, are usually thought to be best regulated by democratically elected parliaments, allowing the sensitive balancing of contradictory interests to be performed in a transparent and accountable manner. The European Convention on Human Rights, the *EU* Charter and for example the Swedish Constitution all set out procedures for

74 Article 40.2 of the General Data Protection Regulation 2016/679.

75 Article 40.5–11 of the General Data Protection Regulation 2016/679.

76 Scharpf (n 5) 7–13 and section 1.

77 Jane Reichel, ‘The Need for a Legitimate Regulatory Regime in Bioethics: A Global and European Perspective’ (2013) 78 *Missouri Law Review* 484.

this, including criteria to be taken into account when limiting these rights.⁷⁸ Also within the EU data protection law, emphasis is put on the forms of rules enacted when regulating data privacy rights for the individual. The Court of Justice of the EU recently held that an unpublished protocol set up by two public authorities for transferring data between them was not sufficient.⁷⁹

5.1 *National Research Ethics Committees as Democratically Legitimate Actors for Balancing Conflicting Interests*

As seen above, the role of research ethics committees has been seen as a legitimizing instrument, whereas the national legislators have been able to establish a procedure for balancing the interest of progress in research and the potential harm of the sample donor, data subjects or research subject. In the case of biomedical research, the potential harm normally consists of the risk of losing privacy, having one's data and samples handled in an unwanted manner. The research ethics committees are thus given the delicate task of defining to what extent it could be legitimate to limit the rights to privacy of individuals for the sake of research. If the involvement of research ethics committees at the national level is considered to be the most prominent legitimating measure for protecting human rights within bioethics, what does this mean for cross-border medical research? Do we have to accept the cumbersome procedures of seeking ethical approval from each national ethics committee involved or should we accept new forms of regulation without parliamentary involvement? The choice often seems to be put in a binary form: if international collaboration is what is needed to gain medical advances, this is the regulatory price.

5.2 *EU Research Policies as an Instrument to Regulate Medical Ethics?*

An essential factor in answering the question of this article – whether the standard-setting for bioethics via soft law could be considered valuable and legitimate – concerns the availability of tools the EU has to influence medical research policies in general and administrative cooperation within bioethics in particular. Could the EU legitimately have a say in how the Member States cooperate within the area of research ethics committees, without having any legislative power in that particular field? One evident way for the EU to influence this cooperation is through research funding. As stated by Schenk:

78 Article 8.2 of the European Convention on Human Rights, Article 52 of the EU Charter and chapter 2, section 21–25 of the Swedish Instrument of Government.

79 Case C-201/14 Smaranda Bara et al. v Președintele Casei Naționale de Asigurări de Sănătate, EU:C:2015:638.

the budget also serves to finance activities largely in the areas of research and development, education, cultural affairs and the environment. As the Community lacks more far-reaching legislative competence, grants within these internal policy areas are often the sole instruments for framing and controlling which are available to the Community.⁸⁰

As seen above, within the area of bioethics, the EU has financed projects that aim at developing tools to allow for smoother cooperation within medical researchers. hSERN and EHR4CR are examples of projects with missions to develop and gather soft law tools as standards and codes of conduct. EUCelLex goes even further and aims to provide the Commission with research and data on cell based regenerative medicine that the Commission can use when drafting legislative acts. The BBMRI-ERIC itself further develops standards and good practices to support biomedical researchers in their internal work with legal and ethical issues. By including these projects to the ongoing work of BBMRI-ERIC, projects from the past and present which receive funding from the EU on ethical issues related to medical research will have a platform to communicate beyond each individual project and beyond the research community.

It must be underlined at this point that also at the national level the evaluation of ethical issues related to medical research is not easily regulated via hard law tools. The evaluation in answering the basic question whether the benefit of the proposed research outweighs the risks involved is left to experts within the research ethics committees to resolve in individual cases. As seen above, several international standards have been enacted, laying down principles of how the balancing test should be performed,⁸¹ as well as guidelines developed within research projects.⁸² Globalization has further highlighted the geographical shortcomings of the nation state and its jurisdiction. As Mayrhofer and Prainsack have put it, in the case of transnational and global governance of biobanks, non-legally binding agreements and soft law regularly emerge in the absence of a central regulator.⁸³ Soft law on ethical issues could be seen as a by-product of the harmonizing and standardizing activities of collaborating biobanks.⁸⁴

80 Wolfgang Schenk, 'EC Grant Management as a Challenge for European Administrative Law' in Oswald Jansen and Bettina Schöndorf-Haubold (eds.), *The European Composite Administration* (Intersentia 2011) 384.

81 Section 2.

82 Section 3.2.

83 Mayrhofer and Prainsack (n 27) 64, 70.

84 Ibid 76.

The role of soft law and the extensive use of self-regulation within the area have therefore traditionally been outspoken within biomedical research. However, within the national context the adjudication of experts in the research ethics committees is embedded in the national constitutional setting. If the function of these committees is exchanged by international organs that exist outside such a well-established setting, the issue at stake seems to be whether these organs are capable of ensuring that researchers in international collaborations are not able to by-pass law and ethics at the national level. This is exactly one of the reasons why BBMRI-ERIC included a strong ELSI-component in their work. The question is whether the current legal setting is enough to master the situation.

5.3 Conclusions

The question thus is whether and how the development of soft law tools by the BBMRI-ERIC and others can be considered so valuable to the advancement of biomedical research, that it is deemed legitimate even without a clear legal basis. Many of the projects discussed above focus on the content of the ethical frameworks applied in the ethical assessments of research and set a standard for European researchers to follow in their research. This may be contrasted to the Clinical Trial Directive and now Regulation, where a composite decision-making process has been established that includes the involvement of research ethics committees before placing new drugs on the market.⁸⁵ According to the procedures in the Regulation, Member States will be bound by each other's decisions that authorize clinical trials, unless the Member State chooses to opt out. However, it is merely the procedure as such that is laid down in EU secondary legislation; the actual balancing of interests is carried out within the national context.⁸⁶ The procedures set out in the Regulation thus connect the assessments of national research ethics board with each other. Each ethics committee remains embedded in national law.

85 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, now replaced by, Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use to be applied from Spring 2016.

86 Article 2–4 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use. See further Jane Reichel, 'Transparency in EU research governance? A case study on cross-border biobanking' in Anna-Sara Lind, Jane Reichel and Inger Österdahl (eds.), *Freedom of Speech, The Internet, Privacy and Democracy* (Liber 2015).

The most problematic issue from a democratic in-put legitimacy perspective thus seem to arise from the ambition of the BBMRI-ERIC to be involved in both standard-setting and the actual assessment of ethic compliance within medical research. But, then again, the out-put perspective could to a certain degree compensate.

The issue of administrative collaboration without a clear legal basis is not uncommon within the EU in general.⁸⁷ One of the main driving forces behind the development of a composite administration within the EU is its ability to solve common European problems that are out of reach for the individual entities, the EU and the Member States.⁸⁸ This out-put oriented argument may be considered an important reason to find it legitimate. In my opinion, these arguments are in the long-run not going to be sufficient to compensate for the lack of in-put legitimacy.

First, there is hardly a consensus in regard to the balancing of interests in bioethical matters.⁸⁹ The risk in allowing both the standard-setting and assessment of ethical issues to take place within an international organization like the BBMRI-ERIC is thus connected to the lack of an open and transparent forum for democratic deliberation. This is especially relevant in relation to ethical issues, also including the protection of fundamental rights, as these may only be limited by procedures decided upon by democratically elected parliaments, where the balancing of sensitive and conflicting interests is performed in a transparent and accountable manner. It is not evident that an organization like the BBMRI-ERIC has the same aim for developing standards and procedures for ethics checks as a national parliament would have. As was pointed out above, the reasons for the BBMRI-ERIC to introduce an ethics check does seem – at least partially – driven by the interest to persuade researchers to share their assets; not merely to protect the interest of the sample donors. Furthermore, the constitutional setting of the European administrative area as such is problematic. A specific feature of this administration is its fragmented structure; the organization and inter-relationships between its constituent bodies vary from one policy area to another.⁹⁰ This heterogeneous

87 Eberhard Schmidt-Aßmann, 'Introduction: European Composite Administration and the Role of European Administrative law' in Oswald Jansen and Bettina Schöndorf-Haubold, *The European Composite Administration* (Intersentia 2011).

88 Herwig C.H. Hofmann and Alexander H. Türk, 'The Development of Integrated Administration in the EU and its Consequences' (2007) 13 *European Law Journal* 253, 262.

89 As Rynning holds, even if the EU would have legislative competence, it is unlikely that European consensus could be reached on the more controversial issues related to policies for research involving human subjects or human biological materials (n 12) 305.

90 Herwig C.H. Hofmann, Gerard C. Rowe and Alexander H. Türk, *Administrative Law and Policy of the European Union* (Oxford University Press 2011) 908–911.

administrative model, with its indistinct boundaries between the European and national, is hardly an ideal arena for transparent and well balanced regulatory work, in one area at the time.

To conclude, there is a strong out-put legitimacy in the work of *BBMRI-ERIC ELSI-CS*. The soft law tools developed are invaluable in order to achieve a high level of ethical compliance in the diverse and scattered legal landscape of the European Research Area. The bottom-up regulatory approach in introducing a common European standard of ethics for biobanking fits well with the tradition of self-regulation that has been applied in the area for a long time. As pointed out by Kaye, the nationally based governance bodies in the field of biobanking are not that well equipped in adjudicating the complex issues involved, such as privacy and disclosure risks that are raised by cross-border data sharing.⁹¹ If the common standards are accepted and respected by the competent research ethics committees on their merits, it could significantly ease the administrative burden on European biobankers.

There may also be an important window of opportunity in the recently enacted General Data Protection Regulation, opening up for the possibility of organization to adopt codes of conduct for processing of data. The procedure laid down in Article 40 of the General Data Protection will thus provide for a legal basis, allowing organizations such as the *BBMRI-ERIC* to enact binding codes in a procedure involving competent authorities on both national and European level. In-put legitimacy could thereby be gained. These codes of conducts would however only cover the processing of data in a cross-border situation, not the handling of samples.

Outside this procedure, the role of *BBMRI-ERIC ELSI-CS* is thus best understood as complementary. As long as the connection between fundamental rights and national democratically elected parliaments is to be upheld, it is difficult to see how *BBMRI-ERIC* could legitimately exchange the assessment of the national research ethics committees with a common European ethics check or similar cross-border tools. This would further add to the complexity of an already fragmented legal framework. As pointed out by Harlow, accountability in the national context differ from the global: 'in the modern nation-state, power is "billeted" and powers are "bounded"; in global space, power is diffused to networks of private and public actors, escaping the painfully established controls of democratic government and public law.'⁹² As seen above in section 4.1, the *ERICs* are placed under some supervision of the Commission and 'relevant public authorities'. It may however be questioned whether the

91 Kaye (n 18) 377.

92 Carol Harlow, 'Global Administrative Law: The Quest for Principles and Values' (2006) 17 *EJIL* 212.

Commission would be well-placed to monitor an ethics review conducted by the BBMRI-ERIC on a research proposal that is to be carried out in a cross-border context.

One test of the robustness of an administrative system is its capability to handle a potential scandal within its area. What happens if something goes very wrong, who is responsible, accountable and may legitimately set things right again? Within the administrative structures of BBMRI-ERIC, it is not all that easy to say.