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# The Need for a Legitimate Regulatory Regime in Bioethics: A Global and European Perspective

*Jane Reichel\**

## ABSTRACT

Bioethics in global biobanking touches upon several internationally accepted fundamental rights and values, namely the sample donor's right of privacy, the patient's right to health, and – at least implicitly – scientific freedom. From the perspective of fundamental rights, however, there are very few internationally applicable rules as to the enforcement of these rights at the administrative level. Instead, the combination of the practical need for common rules and the lack of political will and/or legislative competence within the international community or the European Union (EU) seems to have paved the way for soft law. Further, the role of courts in the area of bioethics and biobanking, nationally as well as internationally, is limited. The implementation of administrative rules at the national or regional levels is carried out by research committees and research funding institutions, usually with limited or no right to appeal to the general court system. Consequently, the traditional mechanisms of political and judicial control to a large extent are unavailable. The question raised here is whether the theories connected to global administrative law can be of any guidance in developing a legitimate regulatory regime for international biobanking. Can principles of participation, transparency, and reasoned decisions be of relevance in this area of law?

## I. INTRODUCTION

Globalization and general technical developments have brought about changes in medical research. It is now possible to collect blood, tissue or other biological samples from large populations of individuals and use them for a series of different research projects in the quest of developing new treatments for diseases and for improving health. After they are collected directly for research purposes or during the course of medical treatment,

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many millions of samples are stored away in freezers (“biobanks”) for future purposes. Medical research using these biobank samples is a typical example of an area where globalization is noticeable, since this research, both in academia and in the pharmaceutical industries, is often conducted across national borders. Samples of human biological material are sent from a research lab in one country to a research lab in another.

On the technical side, methods for freezing and storing samples and other safety assessments are largely regulated by detailed international standards, as developed by the Organization for Economic Co-operation and Development (OECD) and the EU among other organizations.<sup>1</sup> On the ethical side of biological and medical research – bioethics – there are several questions that are not as easily resolved in an international legal context. On one hand, research conducted on humans can be regarded as sensitive from an ethical aspect. On the other hand, there is an enormous public demand for medical achievements, and the public at large is usually willing to contribute to this by donating samples to qualified and reliable researchers.<sup>2</sup> The starting point in this Article is that if researchers are to be considered reliable and gain and retain the trust of the public, a clear legal and ethical framework for medical researchers to act within must be established.

From an integrity perspective, the law as it stands today often sets certain limits as to what can be done with the human body, even a blood or tissue sample, as well as the personal information that may be retrieved from the sample.<sup>3</sup> Several international documents, conventions, and even non-binding declarations state that the donor must give some form of informed consent in order for the research conducted on the sample to be deemed legitimate.<sup>4</sup> For the sample donor to be informed, he or she has to be provided with information on how the sample may be used in the future. Beyond this basic point, however, member states of the international community, or even of the European Union for that matter, have been unable to establish universally accepted ethical standards or common administrative procedures for researchers acting globally. When it comes to ethical issues directly related to

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1. See, e.g., OECD CONSENSUS DOCUMENTS, SAFETY ASSESSMENT OF TRANSGENIC ORGANISMS (2010); 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).

2. Joanna Stjernschantz Forsberg, Mats G. Hansson & Stefan Eriksson, *Biobank Research: Who Benefits from Individual Consent?*, BRIT. MED. J., Oct. 4, 2011, at 1, 1.

3. See *id.*

4. See MATTHIAS RUFFERT & SEBASTIAN STEINECKE, THE GLOBAL ADMINISTRATIVE LAW OF SCIENCE 94-96 (2011). Matthias Ruffert and Sebastian Steinecke have described this as one of the two legal prescriptions within bioethics that has found ‘overall’ acceptance, the other being the prohibition of the reproduction of human beings. *Id.*

biobanks, there are merely soft law documents and no binding legal rules at the global level.<sup>5</sup> National legislators, neither parliaments nor other rule-making bodies entrusted with delegated legislative powers, cannot single-handedly regulate cross-border matters. The regulatory framework applicable in the area of bioethics in international biobanking thus consists of basic principles laid down in public international law, an abundance of non-binding soft law documents, as well as scattered regional and national legislative acts to be applied within the respective legal order.

At the administrative level, ethical issues related to medical research are normally handled within each state in accordance with national law. The procedure varies between states, but basically researchers gather consents from sample donors in standardized forms, which are then reviewed by the competent ethical review committees in the region or the state where the research is being conducted. If the samples are collected in several states, the procedure has to be repeated in each state. On the other hand, if a sample is collected in one state and sent to another, the consent given in the sending state can be considered sufficient, if the receiving state agrees to respect the rules of the sending state.

The focus of this Article is on the international and European administrative rules connected to research on human biological samples in an international context. The administrative burden on international research in the present system often becomes quite onerous, and from the point of view of researchers, there is a need for a foreseeable and transparent internationally applicable regulatory framework on ethical issues. The question is who can regulate this field and how. The ethical and moral values involved in medical research often have a strong connection to the legal, moral, and cultural landscapes of the nation state or region, and it is difficult to find a common denominator acceptable on a global scale. Without the democratic legitimacy of national parliaments, and the lack of a legitimate and competent legislator at the global level, it may be questioned whether soft law is the only possible way forward. However soft the “law” is on its surface, internationally enacted declarations and guidelines often have normative qualities in practice. This article analyzes the form and status of the rules applicable in the field and by which bodies they have been adopted. This analysis takes into account the developing theories on global administrative law, examining what roles the classic administrative rights of transparency, participation, and accountability can have in the current regulatory framework for international biobanking, with its multitude of actors, legislators and rule-makers at different levels.<sup>6</sup>

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5. See *infra* Part III.

6. See *infra* Part II.A.

## II. THE DEVELOPMENT OF A GLOBAL ADMINISTRATIVE LAW AND ITS REGULATORY LIMITS

A central issue for administrative regulations in a globalized context is determining the optimal level for enacting the regulations, and, if an international level is considered necessary, what requirements can be imposed on the globalized regulatory process. The question of the legitimacy of the administrative regulatory powers outside the nation state is central to such discussions. Professor Carol Harlow argues that the legitimizing principles “of any Western administrative system are found in the twin ideals of democracy and the rule of law.”<sup>7</sup> How can these ideals be achieved in a globalized context?

This topic is first discussed from a global perspective and then from the EU perspective. EU regulation is not typical of global administrative law, because the EU itself has evolved into an organization with clear supranational features, with its own legislative, administrative and judicial bodies. From a national perspective, it is still clear that the sources of law deriving from EU law differ from purely national legal sources. The aim of this Article is not to give an exhaustive account of all relevant procedures, but rather to depict the overall regulatory background for further discussions on legitimacy and accountability from the perspectives of researchers and donors.

### A. Administrative Regulation through Public International Law

There is no single set of legislative rules or procedure for the international community. Public international law builds on the premise that no state can be bound to follow rules it has not consented to, i.e. consensual rulemaking. The same concept is true for non-governmental organizations and private enterprises, which cannot be forced to enter into agreements that they do not accept. On the other hand, the era of globalization has brought about a new legal reality with an outspoken need for workable administrative regimes allowing states, NGOs, commercial actors, and individuals around the globe to cooperate, for example, in research projects. Global administrative regimes may thus answer to a practical need of resolving common problems.<sup>8</sup> In areas such as medical research and biobanking, there is further a need for these global administrative regimes to be reliable from a legitimacy perspective, in order for the public not to lose its confidence in the research conducted. Without public faith in the research conducted, there is a risk that

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7. Carol Harlow, *Global Administrative Law: The Quest for Principles and Values*, 17 EUR. J. INT'L L. 187, 190 (2006).

8. Sabino Cassese, *Administrative Law Without the State? The Challenge of Global Regulation*, 37 N.Y.U. J. INT'L L. & POL. 663, 671 (2005). For a discussion on a possible development from a theoretical perspective, see Benedict Kingsbury, *The Concept of 'Law' in Global Administrative Law*, 20 EUR. J. INT'L L. 23 (2009).

fewer donors will consent to donate their samples, which would be detrimental for medical research in general.

Drawing on the terminology established by Professor Fritz Scharpf in connection to the EU, one could differentiate between in-put legitimacy and out-put legitimacy.<sup>9</sup> 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.<sup>10</sup> On the other hand, internationalization has brought about the need for common solutions to solve common problems, and regulations that answer to the very needs of the society can be appreciated as legitimate on the out-put side. The absence of political accountability to a certain extent can be redressed by the effectiveness in achieving consensual goals, where the emphasis on goals being consensual in themselves includes an important restraint on possible objects of regulation.<sup>11</sup> The idea is that the people can be willing to accept solutions that redress actual problems in their daily lives, but only as long as the solutions are in line with what can be considered a consensual goal of their society.

These issues have been discussed in the legal literature under headings such as “constitutionalism,” “global constitutional,” or “administrative law,” where the consequences of the internationalization of public law and the diminishing role of the nation states at the global level have been analyzed.<sup>12</sup> Whereas different theories regarding constitutionalism strive to analyze the role of constitutional hierarchies, principles, and values in a global context,<sup>13</sup> theories on global administrative law have taken a more limited perspective. As presented by Professor Benedict Kingsbury, Professor Nico Krisch, and Professor Richard Stewart, the focus is placed on regulatory and accountability mechanisms:

These developments lead us to define global administrative law as comprising the mechanisms, principles, practices, and supporting social understandings that promote or otherwise affect the accountability of global administrative bodies, in particular by ensuring

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9. FRITZ W. SCHARPF, GOVERNING IN EUROPE: EFFECTIVE AND DEMOCRATIC? 7-13(1999).

10. *See id.* at 7.

11. *Id.* at 22-23.

12. There is a vast literature on the subject, but two recent anthologies can be mentioned: GLOBAL ADMINISTRATIVE LAW AND EU ADMINISTRATIVE LAW (Edoardo Chiti & Bernardo Giorgio Mattarella eds., 2011); THE TWILIGHT OF CONSTITUTIONALISM? (Petra Dobner & Martin Loughlin eds., 2010).

13. *See, e.g.*, Martin Loughlin, *What is Constitutionalism?*, in THE TWILIGHT OF CONSTITUTIONALISM, *supra* note 12, at 47; Armin von Bogdandy, *Constitutional Principles*, in PRINCIPLES OF EUROPEAN CONSTITUTIONAL LAW 3 (Armin von Bogdandy & Jürgen Bast eds., 2006); Gianluigi Palombella, *The Rule of Law Beyond the State: Failures, Promises and Theory*, 7 INT'L J. CONST. L. 442 (2009).

they meet adequate standards of transparency, participation, reasoned decision, and legality, and by providing effective review of the rules and decisions they make. Global administrative bodies include formal intergovernmental regulatory bodies, informal intergovernmental regulatory networks and coordination arrangements, national regulatory bodies operating with reference to an international intergovernmental regime, hybrid public-private regulatory bodies, and some private regulatory bodies exercising transnational governance functions of particular public significance.<sup>14</sup>

The central issues to be studied are thus the rule-making and decision-making procedures of the global administrative bodies, and in what ways they uphold participatory principles, legal reasoning and grounds, and accountability mechanisms. This understanding of the role and the concept of law in a global administrative setting is not contested.<sup>15</sup> The aim of global administrative law, as understood here, is not holistic, in a constitutional sense, but to “focus on global accountability mechanisms of an administrative-law style but retain awareness of the institutional context in which those mechanism are embedded and the broader normative questions they raise.”<sup>16</sup> Even though the application of administrative procedural safeguards in connection to global administrative regimes cannot in itself be expected to render the regimes legitimate,<sup>17</sup> the procedural safeguards may be used as a vehicle to scrutinize the regimes and thereby provide better conditions for other accountability mechanisms at different levels. For the purposes of this Article, this perspective on global regulatory regimes is considered fruitful.

### B. EU Regulatory Powers

Within the EU, the conditions for enacting regulations are quite different than at the global level. The competence of the EU to enact binding acts is regulated by the principle of conferred powers, set out in Article 5.2 Treaty of the European Union (TEU).<sup>18</sup> According to Article 5.2, the EU “shall act only within the limits of the competences conferred upon it by the Member States,” and competences not conferred upon the EU “remain with the Mem-

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14. Benedict Kingsbury, Nico Krish & Richard B. Stewart, *The Emergence of Global Administrative Law*, 68 L. & CONTEMPORARY PROBLEMS 15, 16-17 (2005).

15. See generally Ming-Sung Kuo, *The Concept of ‘Law’ in Global Administrative Law: A Reply to Benedict Kingsbury*, 20 EUR. J. INT’L L. 997 (2009); see also Harlow, *supra* note 7, at 190.

16. Nico Kirsch, *Global Administrative Law and the Constitutional Ambition, in THE TWILIGHT OF CONSTITUTIONALISM?*, *supra* note 12, at 245, 261.

17. Harlow, *supra* note 7, 198.

18. Consolidated Versions of the Treaty on European Union, Official Journal 2012 No. C 326, 1 [hereinafter TEU].

ber States.”<sup>19</sup> The specific articles conferring legislative powers to the EU are found primarily in the Treaty on the Functioning of the European Union (TFEU), where the requirements for the legislative procedure, voting rules, etc. are also laid down.<sup>20</sup> The invocation of EU competence is governed by the principles of subsidiarity and proportionality (Articles 5.3 and 5.4 TEU).<sup>21</sup> For the purposes of this study, the former principle is of greatest interest. Within the area of shared powers, that is in areas where both EU and the Member States are competent to legislate, the principle of subsidiarity holds that the EU

shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.<sup>22</sup>

Once it is established that the EU does have competence to act within an area of law, the main issue then is if it is appropriate for the EU to act, i.e. that there is a sufficient political will. Within the institutional setting of the EU, often referred to as the “Community Method,” the right of initiative has traditionally been given to the Commission.<sup>23</sup> Legislative power is divided between two institutions, the Council and European Parliament.<sup>24</sup> Both are democratically accountable to the union citizens – the European Parliament through direct elections and the Council indirectly via the national level.<sup>25</sup> It is also possible to delegate legislative competence to the Commission to adopt general acts,<sup>26</sup> and in some circumstances, together with national representatives in EU committees.<sup>27</sup>

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19. *Id.*

20. See Consolidated Versions of the Treaty on the Functioning of the European Union, Official Journal 2012 No. C 326, 1 [hereinafter TFEU].

21. TEU, *supra* note 18, at arts. 5.3, 5.4.

22. *Id.* art. 5.3.

23. Youri Devuyt, *The European Union's Institutional Balance After the Treaty of Lisbon: "Community Method" and "Democratic Deficit" Reassessed*, 39 GEO. J. INT'L L. 247, 251-52 (2008). Until the Lisbon Treaty of 2009, the Commission had an exclusive right in this field within the former first pillar, the European Community. *Id.* at 264-65. Today, a certain number of Member States may initiate proposals within the foreign policy, TEU art. 30, and legislation in the field of judicial cooperation in criminal matters and in police cooperation, TFEU art. 76. Further, the Council has in certain circumstances been given the power to amend the proposals from the Commission without unanimity. *Id.* art. 293.

24. TFEU, *supra* note 20, at art. 289.

25. TEU, *supra* note 18, at art. 10.

26. TFEU, *supra* note 20, at arts. 290-91.

27. The procedures are laid down in Regulation (EU) No 182/2011 of the European Parliament and the Council lays down the rules and general principles concern-



The Lisbon Treaty also introduced new mechanisms for allowing actors outside the EU institutional framework to participate. In Article 12(b) TEU, national parliaments are invited to contribute actively to the good functioning of the EU by ensuring that the principle of subsidiarity is respected within the legislative process.<sup>28</sup> This procedure does not constitute a right of veto for the national parliaments but can rather be seen as an institutionalized forum for debate between the Commission and the national parliaments.<sup>29</sup>

Further, Union citizens themselves are invited to participate in initiating legislative projects within the EU. Article 11 TEU introduces a form of participatory democracy as part of the democratic basis of the EU, in addition to the more traditional forms of representation set out in Article 10 TEU.<sup>30</sup> The EU institutions are to give, by appropriate means, citizens and representative associations the opportunity to make known and publicly exchange their views in all areas of Union action.

Outside the area of legally binding rules, EU institutions are often involved in enacting softer forms of rules such as non-legally binding documents referred to as guidelines, recommendations, opinions, etc. As discussed below, there is, for example, a European Group on Ethics on Sciences and New Technologies (EGE), which gives guidance to the Commission and the EU legislature on ethical issues. The enactment of soft law does not follow the procedures described above, at least not directly. As part of the EU, the EGE and other similar groups are, however, considered bound by the overarching aims of the Union, as set out in Article 2 TEU, which demands respect for human dignity, freedom, democracy, equality, the rule of law, and respect for human rights.<sup>31</sup>

Thus, the EU can enact legally binding rules, but only within the area where the Member States actually have transferred powers to it. The actors involved in the legislative procedure may vary, but the today most acts will be enacted by the European Parliament and the Council together. Further, the national parliaments of the Member States have been given a formal, but limited role in the procedures. Outside the area of legally binding rules, the EU is not seldom involved in the development of non-binding rules, soft-law,

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ing mechanisms for control by Member States of the Commission's exercise of implementing powers. Regulation 182/2011, 2011 O.J. (L 55) (EU).

28. TEU, *supra* note 18, at art. 12(b).

29. The procedure is laid down in the Protocol on the Application of the Principles of Subsidiarity and Proportionality, appended to the Lisbon Treaty. Protocol on the Application of the Principles of Subsidiarity and Proportionality, Dec. 13, 2007, 2007 O.J. (C 306); *see also* Gavin Barrett, *Introduction – A New Improved Formula? The Treaty of Lisbon and National Parliaments*, in NATIONAL PARLIAMENTS AND THE EUROPEAN UNION: THE CONSTITUTIONAL CHALLENGE FOR THE OIREACHTAS AND OTHER MEMBER STATE LEGISLATURES (Gavin Barrett ed., 2008).

30. Joana Mendes, *Participation and the Role of Law After Lisbon: A Legal View on Article 11 TEU*, 48 COMMON MKT. L. REV. 1849, 1859 (2011).

31. TEU, *supra* note 18, at art. 2.

where the requirement of transfer of power from the Member States is less relevant.

### III. SETTING THE SCENE – AVAILABLE LEGAL SOURCES ON ETHICS IN BIOBANKING AND RULES OF THEIR APPLICABILITY

When administrative matters move beyond the state, there are basically two methods for deciding which rules are to be applicable; either a common understanding of the rules to be applied can be developed, so that administrative actors apply the same or similar rules, or administrative actors keep to their own rules and develop meta-rules as to when to apply what set of rules.<sup>32</sup> Alternatively, Professors Matthias Ruffert and Sebastian Steinekke, providing an example suitable for this article, stated that

[t]he execution of a bio-ethically doubtful research project by a multinational research institution could be governed either by the bio-ethical rules of an international organi[z]ation or by conflicting rules of different States (the State where the institution is seated, where the project is mainly performed, [or] where the researchers originate from . . .).<sup>33</sup>

These two methods are not mutually exclusive but may interact in an intricate manner. In the following sections, international rules on bioethical issues are presented – first, international rules on fundamental rights in Section A, and then, international rules on administrative matters in Section B. The national level is discussed in Section C, together with rules of conflict in administrative matters.

#### *A. Fundamental Rights in Global and European Legal Sources*

The notion that individuals have the right to decide if and how parts or samples of their body are to be used in medical research is strong in the international community. In practice, it is not merely the actual samples that are considered sensitive, but also the information that can be retrieved from them. The autonomy rights of individuals involved in medical research also involve

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32. The notion of dividing administrative cooperation beyond the state into either networks or conflicts of law was presented by Vilhem Persson and Henrik Wenander, both at the Law Faculty of Lund University, Sweden, at a colloquium held in Uppsala, Sweden, on the 27-28 of March, 2012. Vilhem Persson & Henrik Wenander, Lund Univ., *Administrative Law Beyond the State* (Mar. 27, 2012); see also Henrik Wenander, *Recognition of Foreign Administrative Decisions: Balancing International Cooperation, National Self-Determination, and Individual Rights*, 71 *ZaöRV* 755 (2011).

33. RUFFERT & STEINECKE, *supra* note 4, at 20.

a right to privacy and data protection. General guidance can be found in the Universal Declaration of Human Rights (UDHR) and the International Covenant on Civil and Political Rights (ICCPR), both adopted by the UN in 1948 and 1966, respectively.<sup>34</sup> Especially relevant is Article 1 UDHR, referring to the dignity of all human beings, and Article 7 ICCPR, stating that no one shall be subjected without his free consent to medical or scientific experimentation. Medical research on samples of biological material in a biobank can probably not be regarded as medical or scientific experimentation in the meaning of Article 7 ICCPR.<sup>35</sup>

Thus, when it comes to ethical issues directly related to biobanks, there are merely soft law documents and no binding legal rules at the global level.<sup>36</sup> A central document is the UNESCO Universal Declaration on Bioethics and Human Rights. Its Article 6 states that the right of autonomy of every person to decide on participating in research, for example by donating samples, should be protected,<sup>37</sup> and its Article 9 concerns the protection of privacy of the persons concerned and the confidentiality of personal information.<sup>38</sup> Further, section 1(D) of the OECD Guidelines for Human Biobanks and Genetic Research sets out, as a founding principle, the protection of participants' privacy and the confidentiality of data as founding principles, while section 4(B) requires informed consent.<sup>39</sup>

However, at the European level there are also some binding legal acts.<sup>40</sup> The Council of Europe has adopted two acts that contain general provision on rights to privacy, health and dignity, namely the European Convention for the Protection of Human Rights and Fundamental Freedoms from 1950 and the Social Charter from 1961, revised and expanded in 1996.<sup>41</sup> In 1997 the Council of Europe further adopted the Convention on Human Rights and Medicine, with more specific requirements for informed consent (Articles 5-

34. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(111) (Dec. 10, 1948); International Covenant on Civil and Political Rights, G.A. Res. 2200A (XXI), U.N. Doc. A/6316 (1966).

35. The General Comment No. 20 Replaces General Comment 7 concerning prohibition of torture and cruel treatment or punishment (Art. 7) (Mar. 10, 1992), does not contain any clarification on this point. In paragraph 5 it is, however, held that Article 7 not only relates to acts that cause physical pain but also to acts that cause mental suffering of the victim. *Id.* The description does not seem to fit the situation of a typical biobank sample donor.

36. Elisabeth Rynning, *Legal Challenges and Strategies in the Regulation of Research Biobanking*, in *THE ETHICS OF RESEARCH BIOBANKING* 277, 303 (Jan Helge Solbakk, Søren Holm & Bjørn Hofmann eds., 2009).

37. Universal Declaration on Bioethics and Human Rights, G.C. Res. 33/36, art. 6.

38. *Id.* art. 9.

39. See Rynning, *supra* note 36, at 303.

40. See *id.* at 303-06.

41. *Id.* at 304.

9) and rights to privacy and to information (Article 10). In the EU, the Charter of Fundamental Rights, legally binding since the Lisbon Treaty in 2009, contains several relevant articles. Article 3 states the right of each individual to integrity within the fields of medicine and biology, based on informed consent, and Article 8 grants the right to the protection of personal data.

Fundamental rights other than autonomy rights may also be relevant in the field of ethics in biobanking. The right to the enjoyment of the highest attainable standard of physical and mental health was first articulated in the 1946 Constitution of the World Health Organization (WHO), and the right to health is also included in the United Nations Universal Declaration of Human Rights from 1948 (Article 25) and in the United Nations International Covenant on Economic, Social and Cultural Rights from 1966 (Article 12). In Europe, the right to health is protected in the Council of Europe Social Charter (Article 11) and in an equivalent manner, in the EU Charter of Fundamental rights (Articles 34 and 35).<sup>42</sup> Therefore, it might be argued that if there is a right for individuals, as current and future patients, to enjoy a high standard of health, there is at least a valid interest of promoting medical research.

On the other hand, researchers themselves can also benefit from certain protections, since scientific freedom is also protected in several international treaties. The 1948 Universal Declaration on Human Rights includes a right to share in scientific advancements and benefits, which is not exactly directed at researchers themselves. The International Covenant on Economic, Social and Cultural Rights contains an obligation for the Member States to “respect the freedom indispensable for scientific research and creative activity.”<sup>43</sup> The EU Charter of Fundamental Rights declares in its Article 13 that the arts and scientific research shall be free of constraint. Framed through these articles, scientific freedom is scarcely an individual right for researchers to rely on, but nevertheless, there is a recognition of the importance and value of science.<sup>44</sup>

### *B. International Administrative Regulation*

At the level of fundamental rights, there are hardly any international or European sources directly containing binding administrative rules concerning cross-border biobanking.<sup>45</sup> Rather, EU law contains secondary legislation that may be applied in connection to biobanking, discussed below in Part

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42. Anna-Sara Lind, *The Right to Health from a Constitutional Perspective – The Example of the Nordic Countries*, in *NORDIC HEALTH LAW IN A EUROPEAN CONTEXT* 67, 69 (Elisabeth Rynning & Mette Hartlev eds., 2011).

43. International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200 (XXI), U.N. Doc. A/6316 (1966).

44. RUFFERT & STEINECKE, *supra* note 4, at 30-31.

45. Rynning, *supra* note 36, 302-03.

III.B.1. The main source, however, consists of soft law, discussed in Part III.B.2.

### 1. Secondary EU Law

Within the EU, there is some secondary legislation, that is, legislation enacted by the EU institutions, that applies to biobanking, at least indirectly. This is due to the lack of any specific legal basis conferring competence to the EU to regulate ethical issues. Article 168 Treaty on the Functioning of the European Union (TFEU) contains a legal basis for the EU in the field of public health, but the competence is limited in several ways and does not confer any basis for enacting rules on ethical issues directly.<sup>46</sup> Further, it has proven difficult for the Member States to reach workable agreements on issues affecting ethical or moral issues, as illustrated by the “moral clause” in the Biopatent Directive<sup>47</sup> and the legal framework concerning genetically modified organisms (GMO).<sup>48</sup>

EU law does, however, contain two secondary legislative acts relevant to, if not directly regulative of, the area of bioethics: the Data Protection Directive (DPD)<sup>49</sup> and the above-mentioned Biopatent Directive.<sup>50</sup> The DPD, currently undergoing revision,<sup>51</sup> has the dual aim of both protecting the free

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46. See, e.g., *Amended Proposal for a Directive of the European Parliament and of the Council on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Storage, and Distribution of Human Tissues and Cells*, at 4, COM (2003) 340 final (May 28, 2003) (rejecting certain proposals from the European Parliaments on ethical issues, on the grounds that Article 168 TFEU, which at the time was Article 152 EC, does not give the EU competence in that field); see also Helen Busby, Tamara Hervey & Alison Mohr, *Ethical EU Law? The Influence of the European Group on Ethics in Science and New Technologies*, 33 EUR. L. REV. 803, 820 (2008).

47. Council Directive 98/44/EC, art. 6, 1998 O.J. (L 213) 13, 18. The Directive has been the object for an extensive legal debate. See, e.g., EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS (Aurora Plomer & Paul Torremans eds., 2009); Case C-34/10, *Oliver Brüstle v. Greenpeace e.V.*, 2011 EUR-Lex CELEX LEXIS 2599 (Oct. 18, 2011); Case C-377/98, *Netherlands v. Parliament*, 2001 E.C.R. I-7079.

48. See, e.g., Council Directive 2001/18/EC, 2001 O.J. (L 106) 1 (discussing the deliberate release into the environment of genetically modified organisms). This directive has also been the target of academic debate. See, e.g., Nico Krisch, *The Pluralism of Global Administrative Law*, 17 EUR. J. INT'L L. 247, 256 (2006); Case C-165/08, *Commission v. Poland*, 2009 E.C.R. I-6843.

49. Council Directive 95/46/EC, 1995 O.J. (L 281) (discussing the protection of individuals with regard to the processing of personal data and on the free movement of such data).

50. Rynning, *supra* note 36, at 305.

51. *Commission Proposal for a Regulation of the European Parliament and of the Council on the Protection of Individuals with Regard to the Processing of Per-*

flow of personal data between Member States while at the same time, upholding a high level of protection for the privacy of data objects. Since the transfer of samples in international medical research normally also includes the transfer of personal data, the DPD is highly relevant. The impact of the DPD is discussed further below in Part III.C. Other regulatory measures also affect this area indirectly, such as the decision on the Seventh Frame Work Programs for research, which states that all research shall be carried out in compliance with fundamental ethical principles.<sup>52</sup> According to the preamble of this decision, the opinions of the EGE will be taken into account.<sup>53</sup>

## 2. Soft Law

The main source for administrative practices in the area of ethics in international biobanking is soft law, as issued by international organizations as well as NGOs. One reason for this may be that this is a sensitive area to many countries, which makes it difficult to develop common rules. On the other hand, in the area of science, the use of self-regulation and soft law is wide spread. Professors Ruffert and Steinecke have stated that “what is pertinent in the field of science is the prominence of standards generated by private or at least hybrid actors: networks of scientific institutions, professional bodies or other non-state actors.”<sup>54</sup>

An abundance of documents of different sorts exist at the international level in the area of bioethics. Apart from the declarations on human rights as mentioned above in Part III.A, the WHO has also issued guidelines for obtaining informed consent for the procurement and use of human tissues, cells and fluids in research.<sup>55</sup> In collaboration with the Council for International Organizations of Medical Sciences (CIOMS),<sup>56</sup> WHO has further issued two guidelines: the 2002 International Ethical Guidelines for Biomedical Re-

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*sonal Data and on the Free Movement of Such Data (General Data Protection Regulation)*, COM (2012) 11 final (Jan. 25, 2012).

52. Council Decision 1982/2006/EC, concerning the Seventh Framework Program of the European Community for research, technological development and demonstration activities, 2006 O.J. (L 412) 1, 5, art. 6; *see also* Busby, Hervey & Mohr, *supra* note 46, at 833.

53. Council Decision 1982/2006/EC, preamble ¶ 30, 2006 O.J. (L 412); *see also* Aurora Plomer, *The European Group on Ethics: Law, Politics and Limits of Moral Integration in Europe*, 14 EUR. L. J. 839, 847 (2008).

54. RUFFERT & STEINECKE, *supra* note 4, at 115.

55. WORLD HEALTH ORG., SPECIAL PROGRAMME OF RESEARCH, DEVELOPMENT AND RESEARCH TRAINING IN HUMAN REPRODUCTION: GUIDELINE FOR OBTAINING INFORMED CONSENT FOR THE PROCUREMENT AND USE OF HUMAN TISSUES, CELLS AND FLUIDS IN RESEARCH, *available at* [http://www.who.int/reproductivehealth/topics/ethics/human\\_tissue\\_use.pdf](http://www.who.int/reproductivehealth/topics/ethics/human_tissue_use.pdf).

56. *See generally* COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES, <http://www.cioms.ch/>.

search Involving Human Subjects and the 2008 International Ethical Guidelines for Epidemiological Studies. The Council of Europe has issued an additional protocol and an explanatory memorandum to the protocol of the above-mentioned Convention on biomedicine,<sup>57</sup> as well as recommendations that may be relevant to biobanking.<sup>58</sup> The World Medical Association (WMA), an independent confederation of free professional associations for physicians, has enacted several different declarations,<sup>59</sup> of which the Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects is the most important.<sup>60</sup>

At the EU level, there are two advisory groups under the Commission adopting opinions relevant for bioethics: the above mentioned EGE and the Article 29 Data Protection Working Party.<sup>61</sup> The latter advisory group is connected to the DPD and specializes in questions regarding personal data protection.

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57. *Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research*, COUNCIL OF EUR. (Mar. 18, 2013, 4:19 PM), <http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm>; *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research*, COUNCIL OF EUR. COMMITTEE MINISTERS, <http://conventions.coe.int/Treaty/EN/Reports/Html/195.htm> (last visited Apr. 12, 2013).

58. See, e.g., Recommendation REC (2006) 4, available at <https://wcd.coe.int/ViewDoc.jsp?id=977859>; Recommendation No. R (99) 4., available at [http://www.coe.int/t/dg3/healthbioethic/texts\\_and\\_documents/Rec\(99\)4E.pdf](http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Rec(99)4E.pdf).

59. See, e.g., World Med. Ass'n, *WMA Declaration of Lisbon on the Rights of the Patient* (1981), available at <http://www.wma.net/en/30publications/10policies/14/>; World Med. Ass'n, *WMA Statement on Patient Advocacy and Confidentiality* (1993), available at <http://www.wma.net/en/30publications/10policies/a11/index.html>; World Med. Ass'n, *WMA Declaration on Ethical Consideration Regarding Health Databases* (2002), available at <http://www.wma.net/en/30publications/10policies/d1/>; World Med. Ass'n, *WMA Statement Concerning the Relationship Between Physicians and Commercial Enterprises* (2004), available at <http://www.wma.net/en/30publications/10policies/r2/>; World Med. Ass'n, *WMA Statement on Genetics and Medicine* (2005), available at <http://www.wma.net/en/30publications/10policies/g11/>.

60. See Press Release, World Med. Ass'n, Expert Conference to Discuss Revising Declaration of Helsinki (Nov. 28, 2012), available at [http://www.wma.net/en/40news/20archives/2012/2012\\_32/index.html](http://www.wma.net/en/40news/20archives/2012/2012_32/index.html); see also WORLD MEDICAL ASSOCIATION, [www.wma.net](http://www.wma.net) (last visited Mar. 18, 2013).

61. See, e.g., Article 29 Data Protection Working Party, *Working Document on Genetic Data*, 12178/03/EN WP 91 (Mar. 17, 2004), available at [http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2004/wp91\\_en.pdf](http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2004/wp91_en.pdf); European Group on Ethics, *Opinion No. 15 on Ethical Aspects of Human Stem Cell Research and Use*, 2000, available at [http://ec.europa.eu/bepa/European-group-ethics/docs/avis15\\_enpdf](http://ec.europa.eu/bepa/European-group-ethics/docs/avis15_enpdf).

Further, the EU also acts as a “supranational organization in the international field of research.”<sup>62</sup> Since entering into the Lisbon Treaty in 2009, the EU’s competence within this field has strengthened. There is now a legal basis to establish a European research area, characterized by the free circulation of researchers, technological development, and space.<sup>63</sup> In the 2020 Strategy, the EU has defined several steps for achieving a sustainable economy and growth in Europe.<sup>64</sup> One part of the strategy is directed at research and innovations. In line with this work, and even prior to the Lisbon Treaty in 2009, the EU introduced several agencies, programs, and instruments to facilitate research. One example is the European Strategy Forum on Research Infrastructures (EFRSI), a commission formed to support a coherent and strategic policy for research infrastructures in Europe.<sup>65</sup> The Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) was one of the first projects entering the European Research Infrastructure preparatory phase of the ESFRI roadmap, as funded by the commission.<sup>66</sup>

One of the tasks the BBMRI has assumed is giving legal and ethical support to researchers in navigating “the legal pathways that govern its pan European, cross border, multi-jurisdictional infrastructure and operations” by “sharing, discussing, validating and issuing authoritative and reliable legal forms and standards.”<sup>67</sup> Even though the research projects within the BBMRI cannot produce authoritative statements of the law, this work is an illustrative example of the need for guidance by researchers in applying the rather obscure regulatory regimes applicable to cross-border biobanking. And, in an area where common binding international rules are few, but soft law is plenty, standard-setting activities among a large group of researchers may have some normative effect in the long run.<sup>68</sup>

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62. RUFFERT & STEINECKE, *supra* note 4, at 65.

63. TFEU, *supra* note 20, at art. 179.

64. *Communication from the Commission, Europe 2020: A Strategy for Smart, Sustainable and Inclusive Growth*, COM (2010) 2020 final (Mar. 3, 2010).

65. See EUROPEAN STRATEGY FORUM ON RESEARCH INFRASTRUCTURES, [http://ec.europa.eu/research/infrastructures/index\\_en.cfm?pg=esfri](http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=esfri) (last visited Mar. 11, 2012); Moa Beijer, *Soft law i EU – Dess roll inom området för bioetik i EU och BBMRI [Soft Law in the EU – It’s Role in the Area of Bioethics in the EU]*, FT 21012, pp. 135-148.

66. BIOBANKING & BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE, [BBMRI.eu](http://BBMRI.eu) (last visited Mar. 11, 2012). The research for this article has been funded by BBMRI.se, the Swedish part of the infrastructure. BIOBANKING & BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE OF SWEDEN, [BBMRI.se](http://BBMRI.se) (last visited Mar. 18, 2013).

67. See WIKI Legal Platform, BIOBANKING & BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE, [http://www.legalpathways.eu/index.php?option=com\\_joomlawiki](http://www.legalpathways.eu/index.php?option=com_joomlawiki) (last visited Apr. 12, 2013). The research project is currently not active, but there are similar projects running within the BBMRI.se.

68. RUFFERT & STEINECKE, *supra* note 4, at 115.



### C. National Law and Common Principles in its Application

As a general starting point, the assessment of ethical issues in relation to biobanking is carried out by research ethics committees at the national level. All of the above-mentioned guidelines and recommendations require the involvement of ethics committees in some form.<sup>69</sup> In the OECD Guidelines on Human Biobanks and Genetic Research Databases (HBGRD), the use of an independent research ethics committee is one of the main prerequisites of best practices:

The establishment, governance, management, operation, access to, and use of the HBGRD and its protocols and processes for research activities, should be approved or reviewed, as applicable, by an independent research ethics committee.<sup>70</sup>

Professors Ruffert and Steinecke maintain that these types of committees exist in almost all countries.<sup>71</sup> The approval by a research ethics committee will usually include both situations when collecting samples for a specific research project, or when re-using old samples already stored in a biobanks. Standardized forms are usually used when collecting consents from sample donors. These are usually drafted by the researchers themselves, after models made available by associations,<sup>72</sup> the biobanks themselves<sup>73</sup>, or, as discussed above, provided by groups of researchers.<sup>74</sup>

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69. See, e.g., Council for Int'l Organizations of Med. Sciences & World Health Org. [WHO], *International Ethical Guidelines for Epidemiological Studies*, guideline 2 (2002), available at [http://www.cioms.ch/images/stories/CIOMS/guidelines/guidelines\\_nov\\_2002\\_blurb.htm](http://www.cioms.ch/images/stories/CIOMS/guidelines/guidelines_nov_2002_blurb.htm); Council for Int'l Organizations of Med. Sciences & WHO, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, at 24 (2002), available at [http://www.cioms.ch/publications/layout\\_guide2002.pdf](http://www.cioms.ch/publications/layout_guide2002.pdf); Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research*, at art. 9 (2005), available at <http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm>; see also World Med. Ass'n, *Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects*, at 2, 4 (2008), available at <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>.

70. Org. for Econ. Co-Operation & Dev., *OECD Guidelines on Human Biobanks and Genetic Research Databases*, at 5 (2009), available at <http://www.oecd.org/science/biotech/44054609.pdf>.

71. RUFFERT & STEINECKE, *supra* note 4, at 98 n.33.

72. See, e.g., BIOBANK SWEDEN, [www.biobanksverige.se](http://www.biobanksverige.se) (last visited Mar. 10, 2012). In Sweden, the National Biobank Council, consisting of representations from regional municipalities, universities and pharmaceutical industries, provides various model forms on its website. See *id.*

73. See, e.g., BIOBANK UK, [www.ukbiobank.ac.uk](http://www.ukbiobank.ac.uk) (last visited Mar. 10, 2012).

74. See *supra* note 67 and accompanying text.

The transfer of biological samples across borders includes privacy issues both regarding the sample itself and regarding the personal data retrievable from the sample. These two issues are dealt with separately, at least within the EU. Regarding the transfer of the biological material itself, there are, as seen above, no globally applicable administrative rules. As pointed out in the introduction, a research project collecting samples from several states must seek approval from committees in every state.<sup>75</sup> When a sample is to be sent from one state to another, a specific approval from a research committee may also be needed, even though it might not be necessary to obtain a new consent from the donor.<sup>76</sup> The transfer must usually be preceded by entering into an agreement between the sender and receiver, a material transfer agreement (MTA).<sup>77</sup> All the conditions for handling the samples are regulated in the MTA, specific restrictions regarding the given consent, etc.<sup>78</sup> Standardized forms for MTAs are often made available by the same actors providing forms for informed consent.<sup>79</sup>

The transfer of personal data is regulated by the above-mentioned DPD within the EU.<sup>80</sup> The DPD stipulates that sensitive personal data, for example data on a person's health, can be processed freely within the EU, as long as the data subject has consented to it.<sup>81</sup> Transfers of personal data to third countries can be permitted in three situations. First, transfer is permitted if the receiving state ensures an adequate level of protection.<sup>82</sup> The EU Commission has been assigned the task of entering into negotiations with third countries and determining whether a country ensures an adequate level of protection in the meaning of the DPD.<sup>83</sup> In such cases, personal data may be transferred to these countries on the same conditions as within the EU.<sup>84</sup>

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75. For a discussion of the issue, see Mats G. Hansson, Marco Gattorno, Joanna Stjernschantz Forsberg, Nils Feltelius, Alberto Martini & Nicolino Ruperto, *Ethics Bureaucracy: A Significant Hurdle for Collaborative Follow-Up of Drug Effectiveness in Rare Childhood Diseases*, 97 ARCHIVES DISEASE CHILDHOOD 561 (2012).

76. The research ethics committee may, however, require that the sample donor has consented to cross-border transfers as part of the requirement of informed consent given in on collecting the sample. For a description of Swedish law, see BIOBANKSVERIGE, [www.biobanksverige.se](http://www.biobanksverige.se) (last visited Apr. 12, 2013).

77. INT'L SOC'Y FOR BIOLOGICAL & ENVTL. REPOSITORIES, 2012 BEST PRACTICES FOR REPOSITORIES: COLLECTION, STORAGE, RETRIEVAL, AND DISTRIBUTION OF BIOLOGICAL MATERIALS FOR RESEARCH 147 (3d ed. 2011), available at <http://www.isber.org/bp/documents/ISBERBestPractices3rdedition.pdf>.

78. *Id.*

79. *Id.* at 123.

80. *See supra* Part III.B.1.

81. *See* Council Directive 95/46/EC, art. 8.1, 1995 O.J. (L 281) 40 (EU).

82. *See id.* art. 25.1.

83. *See id.* art. 25.5-6. The list of countries that has been found to have an adequate level of protection can be found on the EU website. *Commission Decisions on the Adequacy of the Protection of Personal Data in Third Countries*, EUROPEAN

Second, the Commission may enter into Safe Harbor agreements, allowing transfers of data to specific entities within a state adhering to the principles laid down in the agreement.<sup>85</sup> This type of agreements have in entered into with the United States, for example.<sup>86</sup> If none of these options are available, the third option is to enter into an agreement with the receiving party.<sup>87</sup> The Commission has enacted a decision with standard contractual clauses, containing the necessary set of information to enter into an agreement to transfer personal data outside the EU.<sup>88</sup> These agreements are equivalent to the above-mentioned MTAs and are usually referred to as data transfer agreements (DTA).<sup>89</sup> As stated in the preamble to the Commission decision, the use of the standard contract is voluntary as the clauses are only one of several possibilities under the DPD.<sup>90</sup> However, since there are a number of competing, and to some extent divergent, standard contractual clauses available,<sup>91</sup> the Commission further prescribes that data exporters must stick to one set of standards at a time; that they should not be allowed to amend these sets or totally or partially merge them in any manner.<sup>92</sup>

In both cases, whether a MTA or DTA agreement has been entered into, or data has been transferred by any of the other ways described above, there are no common rules enabling the sending state in practice to monitor or control the use of the samples in the receiving country. Only the receiving country is competent to hold accountable researchers within its borders, outside the control mechanisms built into the peer review system and academic discourse of the research community itself.

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COMMISSION, [http://ec.europa.eu/justice/data-protection/document/international-transfers/adequacy/index\\_en.htm](http://ec.europa.eu/justice/data-protection/document/international-transfers/adequacy/index_en.htm) (last visited Mar. 11, 2013).

84. *Id.*

85. See Council Directive 95/46/EC, art. 26.2, 1995 O.J. (L 281) 40 (EU).

86. Commission Decision 2000/520/EC, 2000 O.J. (L 215) 10 (EU), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:215:0007:EN:PDF>.

87. See Commission Decision 2004/915/EC, 2004 O.J. (L 385) 74 (EU), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:385:0074:0084:EN:PDF>.

88. *Id.* at 77.

89. *Id.*

90. Commission Decision C (2004) 5271, 2004 O.J. (L 385) 74 (EU), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:385:0074:0084:EN:PDF>.

91. The Commission refers to clauses adopted by the International Chamber of Commerce (ICC), Japan Business Council in Europe (JBCE), European Information and Communications Technology Association (EICTA), EU Committee of the American Chamber of Commerce in Belgium (Amcham), Confederation of British Industry (CBI), International Communication Round Table (ICRT) and the Federation of European Direct Marketing Associations (FEDMA). *Id.* at 74 n.3.

92. *Id.* at 74.

#### IV. ANALYSIS

Soft law plays a prominent role in the administrative regimes applicable to global bioethics and biobanking. The combination of practical need and lack of political will and/or legislative competence within the global regime seems to have paved the way for soft law. As stated by Professor Alessandro Spina, this softer form of developing a common understanding of law does not call into question the formal transfer of powers from the national level to the supranational level, and therefore entails less of a commitment for the involved states.<sup>93</sup> In this section the role and function of the soft law instruments will be analyzed.

##### *A. The Current State of Affairs*

The current situation of soft law use is not unproblematic. The necessary minimum set of rules or standards has been developed, allowing global actors to have some sort of foreseeability on the legal requirements for conducting research. However, the soft law instruments available today can be described as multiple, overlapping and incoherent.

Further, as described here, the soft law to some extent can be developed by the researchers themselves, turning the persons targeted by the ethical guidelines into the regulators.

Another prominent feature of biobanking, nationally as well as internationally, is the importance of standardized forms for collecting consents from sample donors and entering into agreements for sending biological samples and personal data. In many cases, the actual protection of privacy of sample donors in practice boils down to the drafting of a form, where the information about the current, or possibly future, research project is set out for the sample donor to consider. These forms are normally reviewed by research ethics committees and, to some extent, research funding institutions, within the administrative procedure at state or regional levels.

In summary, the legal tools available in international biobanking at the administrative level are regulatory acts of low hierarchical legal value, with an extensive use of standardized forms drafted by low-level administrative or hybrid private-public bodies. These are reviewed by other low-level bodies, and at least when involving transferring samples from EU Member States, monitored by versions of the principle of mutual recognition, with very diffuse mechanisms invoked to control what happens to the sample in practice. From a national point of view, this seem to be a rather strange way to regulate issues involving several fundamental rights, namely the right of privacy of the sample donor, the right to health for patients, and – at least

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93. See Alessandro Spina, *The Regulation of Pharmaceuticals Beyond the State*, in GLOBAL ADMINISTRATIVE LAW AND EU ADMINISTRATIVE LAW, *supra* note 12, at 249, 261.

indirectly – scientific freedom. 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, the protection of privacy, and the interest in medical research to be performed by an organ directly accountable to the people. Further, in the areas of bioethics and biobanking, nationally as well as internationally, the role of courts is limited. The implementation of the administrative rules is carried out by research committees, usually with limited or no right to appeal to the regular court system. Thus, the traditional mechanisms of political and judicial control to a large extent are unavailable. The latter, especially, has often been considered an important mechanism in the globalized legal landscape, since the courts are well-equipped for establishing hierarchies between legal norms from different and perhaps competing legal orders, as well as balancing contradictory rights and interests in order to find the rule to apply in the specific case.<sup>94</sup>

On the other hand, soft law might be better than no law. Within global administrative regimes, self-regulating, circular forms of rulemaking in general are not unusual.<sup>95</sup> In the context of bioethics in global biobanking, soft law can play a role that old-school national-based regulatory regimes cannot.

What specific problems do the administrative regulatory regimes of international biobanking encounter? First, biobanking in itself has difficulties fitting into the ethical regulatory framework, even on a national level. Biobanking regulations face several failures; privacy cannot be upheld in longitudinal data collection as this would undermine the scientific value of the biobanks by hindering the use of the same sample on different medical research projects over time.<sup>96</sup> And further, individuals' consent to participate in biobanks cannot be fully informed because the very nature of biobanks is to collect samples for future research uses that may not yet be formulated.<sup>97</sup> In Sweden, one of the largest research projects funded by the Swedish Re-

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94. Krisch, *supra* note 48, at 266-67; Armin von Bogdandy, *Pluralism, Direct Effect, and the Ultimate Say: On the Relationship Between International and Domestic Constitutional Law*, 6 INT'L J. CONST. L. 397, 397-413 (2008); see also Jane Reichel, *European Legal Method from a Swedish Perspective – Rights, Compensation and the Role of the Courts*, in EUROPEAN LEGAL METHOD 245, 267 (Ulla Neergaard, Ruth Nielsen & Lynn Roseberry eds., 2011).

95. Cassese, *supra* note 8, at 669; Mauro Zamboni, *Globalization and Law-Making: Time to Shift a Legal Theory Paradigm*, 1 INT'L J. STUDY LEGIS. 125, 142 (2007).

96. Kieran C. O'Doherty et al., *From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks*, 73 SOC. SCI. & MED. 367, 367 (2011).

97. *Id.*; Mats G. Hansson, Joakim Dillner, Claus R. Bartram, Joyce A. Carlsson & Gert Helgesson, *Should Donors Be Allowed to Give Broad Consent to Future Biobank Research?*, 7 LANCET ONCOLOGY 266 (2006).

search Council, LifeGene, was stopped by the Swedish Data Inspection Board in December 2011, due to this very reason.<sup>98</sup>

### B. A Way Forward

The way forward is to focus on innovative governance and engagement strategies so as not to be held captive by a “contractual interpretation of informed consent documents.”<sup>99</sup> These authors include representativeness, accountability, transparency, reflective practice, and sustainability as necessary conditions for trustworthy biobank governance.<sup>100</sup> Within the EU, an expert group under the Commission has also recently published a report focusing on governance strategies for biobanks.<sup>101</sup> At the global level, the insufficiencies of the regulatory regime may be even harder to reconcile, leading to either what has been described as “ethics bureaucracy”<sup>102</sup> or an uncontrolled use of samples in far-away countries.

Could a focus on governance regimes and global administrative law solutions be a way forward also at the international level? To start with, there is no single regulator who might be asked to uphold the governance principles set out above. On the other hand, as stated by Professor Eduardo Chiti, the lack of a global government or set of higher institutions is one of the factors contributing to the development of the rule of law in the legal space, as the establishment of principles and rules of global administrative law is able to compensate in part for the administration’s own lack of constitutional grounding.<sup>103</sup> This version of the rule of law is apparently different from the traditional nation-state understanding of the concept as one of two twin ideals referred to by Professor Harlow (the other being democracy).<sup>104</sup> The problem, according to Professor Harlow, seems less connected to the application of principles, but rather to the structures of legal globalization; “in global space, power is diffused to networks of private and public actors escaping the painfully established controls of democratic government and public law”.<sup>105</sup> The question to be analyzed here is if legal principles and procedural safeguards can be used as a vehicle to overcome the difficulties in monitoring the disparate use of public power in global space, and is so, how.

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98. Swedish Data Inspection Board decision December 16, 2011, dnr 766-2011.

99. O’Doherty et al., *supra* note 96, at 369.

100. *Id.*

101. See EXPERT GROUP ON DEALING WITH ETHICAL & REG. CHALLENGES INT’L BIOBANK RES., BIOBANKS FOR EUROPE: A CHALLENGE FOR GOVERNANCE (2012), [http://www.coe.int/t/dg3/healthbioethic/Activities/10\\_Biobanks/biobanks\\_for\\_Europe.pdf](http://www.coe.int/t/dg3/healthbioethic/Activities/10_Biobanks/biobanks_for_Europe.pdf).

102. Hansson, Gattorno, Forsberg, Feltelius, Martini & Ruperto, *supra* note 75.

103. Eduardo Chiti, *EU and Global Administrative Organizations*, in GLOBAL ADMINISTRATIVE LAW AND EU ADMINISTRATIVE LAW, *supra* note 12, at 13, 16.

104. Harlow, *supra* note 7, 190; see generally Palombella, *supra* note 13.

105. Harlow, *supra* note 7, at 212.

More precisely, could the idea of basic administrative procedural safeguards, developed in administrative procedures at the global level, however vague, be used in an attempt to connect the global level to the administrative organs and legal orders within region and states, where the use of public powers are under stricter control? Global administrative law does not exist in a vacuum. In the well-known *Kadi* case from the CJEU, the administrative principles of the right to be heard and the right to an effective judicial review played a seminal role in the scrutiny of an EU regulation implementing a UN Security Council resolution.<sup>106</sup> Even if the situation in *Kadi* was exceptional, the underlying idea is worth developing further.

There is, as described above, a tradition of self-regulation in global administrative regimes in general, and the field of medical research is definitely no exception to this. There are strong arguments for why professionals should be involved in the development of ethical guidelines, but that does not exclude the interest of an open and transparent regulatory regime. The role of participation has shifted considerably in the context of globalization,<sup>107</sup> and there is no reason to believe that it cannot also be relevant in the area of bioethics. A point of relevance to this end is raised by Professor Aurora Plomer, who points out the need to scrutinize the appointments of members of influential ethical groups, such as the EGE in the EU.<sup>108</sup>

## V. CONCLUDING REMARKS

The most pressing issue that needs to be addressed is the multiplicity and incoherence of the existing soft law instruments. There is a need to sort among the vast supply of global guidelines, standardized forms, and contractual clauses and to distinguish which sources are relevant to whom and when. Is it possible for administrative procedural safeguards to be applied to ethical or moral value judgments laid down in ethical guidelines? Yes, if the focus is placed on the actors engaged in producing as well as applying the guidelines. As cited above, the EU Commission has stated, in regards to the standard contractual clauses to be applied in transferring personal data to third countries, that data exporters should not be allowed to deviate from one set of standard contractual clauses, and must not amend these sets or totally or partially merge them in any manner. It might seem contradictory to state that a party may not deviate from a non-binding set of rules, since the party can choose not to apply it at all. However, in a regulatory reality such as the pre-

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106. Joined Cases C-402/05 P & C-415/05 P, *Kadi & Al Barakaat v. Council of the European Union and Commission of the European Communities*, 3 C.M.L.R. 41 (2008).

107. See generally Joana Mendes, *Administrative Law Beyond the State: Participation at the Intersection of Legal Systems*, in GLOBAL ADMINISTRATIVE LAW AND EU ADMINISTRATIVE LAW, *supra* note 12, at 111.

108. Plomer, *supra* note 53, at 858.

sent, “the categorical distinction between ‘binding’ and ‘non-binding’ loses its overall importance.”<sup>109</sup> There are, therefore, good reasons for both researchers as well as national and regional administrative bodies to handle this soft law in much the same way as binding rules.

This approach entails a need for administrative bodies that are applying the relevant soft law, i.e. research committees and research funders, to set out the conditions for granting permissions or funding in a clear and unequivocal manner, providing open and transparent procedures, and engaging in dialogues regarding how global regulatory regimes will be applied in the individual case. Decisions should be fully reasoned regarding how different and competing international guidelines have been assessed, and if they have not been found to be relevant, why. These are tasks usually left to courts, but if a court system is not available, other administrative organs must fill that role. By focusing on transparency, participation and the right of the parties concerned to engage in a constructive dialogue regarding the application of global regulatory regimes on bioethics, the conditions for other accountability mechanisms available at the national or regional levels may further be enhanced. National and regional parliaments, ombudspersons and their equivalents must also orient their control as to issues related to global administrative regimes.

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109. RUFFERT & STEINECKE, *supra* note 4, at 114.