

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

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## 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?

## 1 Introduction

Globalisation 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. Many millions of samples are stored away in freezers, “biobanks”, having been collected during the course of medical treatment and then saved for future purposes or directly collected for research purposes. Medical research using samples from biobanks is a typical example of an area where globalisation 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 mostly regulated in detailed international standards, as developed by the OECD and the EU among other organisations.<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

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<sup>1</sup> *See*, for example, OECD Consensus Documents, Safety Assessment of Transgenic Organisms and EU 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.

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 point of departure 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. Several international documents, conventions as well as non-binding declarations, state that the donor must give an informed consent in some form in order for the research conducted on the sample to be deemed legitimate.<sup>3</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 of departure, however, member states of the international community, or even of the European Union, have not been able to establish ethical standards acceptable to all. Nor are there any common administrative procedures for researchers acting globally to follow. 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 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 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, 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 analyses the form and status of the rules applicable in the field and by which organs they have been

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2 Stjernschantz Forsberg, J., Hansson, M. G. & Eriksson, S., *Biobank research: who benefits from individual consent?* BMJ 2011;343:d5647.

3 Ruffert and 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, Ruffert, M. & Steinacke, S., *The Global Administrative Law of Science*, Springer, Heidelberg, 2011, p. 94. See further section 3.1.

adopted. This analysis takes into account global administrative law theories, examining what roles the classic administrative rights of transparency, participation and accountability can have in developing rules on international biobanking.

## **2 The Development of a Global Administrative Law and its Regulatory Limits**

A central issue for administrative regulations in a globalised 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 globalised regulatory process. The question of the legitimacy of the administrative regulatory powers outside the nation state is central to such discussions. 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>4</sup> How can these ideals be achieved in a globalized context?

This topic is here first discussed from a global perspective and then from the EU perspective. EU regulation is not typical of that meant by global administrative law, because the EU itself has evolved into an organization with clear supranational features, with its own legislative, administrative and judicial organs. 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 here 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.

### **2.1 *Administrative Regulation through Public International Law***

There is no single set of legislative rules of 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 is true for non-governmental organisations 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 for 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>5</sup> In areas such as medical

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4 Harlow, C., *Global Administrative Law: The Quest for Principles and Values*, EJIL (2006), Vol. 17 No 1, pp. 187-214, p. 190.

5 Cassese, S., *Administrative Law without the State? The Challenge of Global Regulation*, 37 New York University Journal of International Law and Politics 663 (2005), pp. 663-694. See for a discussion on a possible development from a theoretical perspective, Kingsbury, B., *The Concept of 'Law' in Global Administrative Law*, EJIL (2009), Vol 20 No 1, pp. 23-57.

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. Drawing on the terminology established by Scharpf in connection to the EU, one could differentiate between in-put legitimacy and out-put legitimacy.<sup>6</sup> In a classic nation state setting, legitimacy can be derived through the process of enacting the rules, in-put legitimacy, for example, through the direct or indirect participation of a democratically-elected parliament. On the other hand, internationalisation 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>7</sup>

These issues have been discussed in the legal literature under headings such as constitutionalism, global constitutional or administrative law, where the consequences of the internationalisation of public law and the diminishing role of the nation states at the global level have been analysed.<sup>8</sup> Whereas different theories regarding constitutionalism strive to analyse the role of constitutional hierarchies, principles and values in a global context,<sup>9</sup> theories on global administrative law have taken a more limited perspective. As presented by Kingsbury, Krisch and Stewart, the focus is placed on regulatory and accountability mechanisms:<sup>10</sup>

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 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

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6 Scharpf, F. W., *Governing in Europe: Effective and Democratic?*, Oxford University Press, 1999, p. 11.

7 Ibid, p 22. See further Craig, P., *Legitimacy in European Administrative Law*, Kuffeet, M. (ed.) *Legitimacy in European Administrative Law: Reform and Reconstruction*, Europa Law Publishing, Gronningen, 2011, pp. 208.

8 There is a vast literature on the subject, but two recent anthologies can be mentioned; Dobner, P. & Loughlin, M. (eds), *The Twilight of Constitutionalism*, Oxford University Press, 2010, Chitis, E. & Giorgio Mattarella, B. (eds), *Global Administrative Law and EU Administrative Law. Relationships, Legal Issues and Comparison*, Springer Heidelberg 2011.

9 See, for example, Loughlin, M., *What is Constitutionalism*, Dobner, P. & Loughlin, M. (eds), *The Twilight of Constitutionalism*, Oxford University Press, 2010, Palombella, G., *The rule of law beyond the State: failures, promises and theory*, *International Journal of Constitutional law*, vol 7, no 3, pp. 442–467, von Bogdandy, A., *Constitutional Principles*, in *Principles of European Constitutional law*, von Bogdandy, A. & Bast, J., *Principles of European Constitutional Law*, Hart, Oxford, 2006.

10 *The Emergence of Global Administrative Law*, 68 *Law and Contemporary Problems* 15(2005), pp. 15–61, at p. 17.

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.

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, as well as accountability mechanisms. This understanding of the role and the concept of law in a global administrative setting is not uncontested.<sup>11</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>12</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>13</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.

## 2.2 *EU Regulatory Powers*

Within the EU, the conditions for enacting regulations are quite different. 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). According to this article, 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 Member States. 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 procedure, voting rules, etc. are also laid down.<sup>14</sup> The invocation of EU competence is governed by the principles of subsidiarity and proportionality (Articles 5.3 and 5.4 TEU). 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,

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11 Kuo, M-S, *The concept of ‘Law’ in Global Administrative Law: a reply to Benedict Kingsbury*, EJIL, 2009, 20(4), pp. 997-1004. See also Harlow op cite.

12 Krisch, N., *Global Administrative Law and the Constitutional Ambition*, in Dobner, P. & Loughlin, M. (eds), *The Twilight of Constitutionalism*, Oxford University Press, 2010, pp. 253 and 261.

13 Harlow, op cite, note 4 p. 198.

14 For example, Article 168 TFEU on the field of public health as discussed in section 3.1.

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’.

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>15</sup> The legislative power is divided between two institutions, the Council and European Parliament (Article 289 TFEU), both democratically accountable to the union citizens, the European Parliament through direct elections, and the Council indirectly via the national level (Article 10 TEU). In addition, it is possible to delegate legislative competence to the Commission to adopt general acts, (Article 290 and 291 TFEU), in some circumstances together with national representatives in EU committees.<sup>16</sup>

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 insuring that the principle of subsidiarity is respected within the legislative process. This procedure does not constitute a right of veto for the national parliaments, but can rather be seen as an institutionalised forum for debate between the Commission and the national parliaments.<sup>17</sup>

Union citizens themselves are also 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>18</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.

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15 Devuyst, Y., *The European Union’s Institutional Balance after the Treaty of Lisbon: “Community Method” and “Democratic Deficit” reassessed*, 39 *Geo.J. Int’L.* 247 2007-2008. Until the Lisbon Treaty of 2009, the Commission had an exclusive right in this field within the former first pillar, the European Community. Today, a certain number of Member States may initiate proposals within the foreign policy, Article 30 TEU, and legislation in the field of judicial cooperation in criminal matters and in police cooperation, Article 76 TFEU. Further, the Council has in certain circumstances been given the power to amend the proposals from the Commission without unanimity, Article 293 TFEU.

16 The procedures are laid down in Regulation (EU) No 182/2011 of the European Parliament and if the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers.

17 The procedure is laid down in the Protocol on the Application of the Principles of Subsidiarity and Proportionality, appended to the Lisbon Treaty. See further Barret, G., *Introduction - A New Improved Formula? The Treaty of Lisbon and National Parliaments*, Barrett, G. (ed), *National parliaments and the European Union: the Constitutional Challenge for the Oireachtas and other Member States Legislatures*, Clarus Press, Dublin, 2008.

18 Mendes, J., *Participation and the Role of Law after Lisbon: a Legal View on Article 11 TEU*, *C.M.L.Rev.* Vol. 48, No. 6, 2011, pp. 1849-1878.

Outside the area of legally binding rules, EU institutions are often involved in enacting softer form of rules, 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. Being part of the EU, the EGE and other similar groups must however be considered to be bound by the overarching aims of the Union, as set out in Article 2 TEU, respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights.

### **3 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>19</sup> Or, as stated by Ruffert and Steinecke, referring to an example suitable for this article:<sup>20</sup>

The 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 organisation or by conflicting rules of different States (the State where the institution is seated, where the project is mainly performed, where the researchers originate from...)

These two methods are not mutually exclusive, but may interact in an intricate manner. In the following, international rules on bioethical issues are presented, first international rules on fundamental rights in section 3.1, and then international rules on administrative matters in section 3.2. The national level is discussed in section 3.3, together with rules of conflict in administrative matters.

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19 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. See also Wenander, H., *Recognition of Foreign Administrative Decisions. Balancing International Cooperation, National Self-Determination, and Individual Rights*, *ZaöRV* (2011), pp. 755-785.

20 Ruffert & Steinecke, op cite, note 3, p. 20.

### 3.1 *Fundamental Rights in Global and European Legal Sources*

As mentioned above, 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 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. 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>21</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>22</sup> A central document is the UNESCO Universal Declaration on Bioethics and Human Rights, whose 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, and its Article 9 concerns the protection of privacy of the persons concerned and the confidentiality of personal information. Further, the OECD Guidelines for Human Biobanks and Genetic Research sets out the protection of participants' privacy and the confidentiality of data as founding principles in its section 1D, and information informed consent as a main rule in its section 4.B.

However, at the European level there are also some binding legal acts. 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. In 1997 the Council of Europe further adopted the Convention on Human Rights and Medicine, with more specific requirements for informed consent (Articles 5-9) and rights to privacy and to information (Article 10). In the EU, The Charter of Fundamental Rights, legally binding since the Lisbon Treaty 2009, contains several relevant articles. Article 3 states the right of each individual to integrity

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21 The General Comment No. 20 concerning prohibition of torture and cruel treatment or punishment (Art. 7), : replacing general comment 7, enacted by the Office of the United Nations High Commissioner for Human Rights on the 10 of March 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. The description does not *Seem* to fit the situation of a typical biobank sample donor.

22 Rynning, E., *Legal Challenges and Strategies in the Regulation of Research Biobanking*, J.H. Solbakk, et al. (eds.), *The Ethics of Research Biobanking*, Springer Science+ Business Media, 2009, p. 303.

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 however 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 Nation 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>23</sup>

Further, 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”. The EU Charter of Fundamental Rights declares in its Article 13 that the arts and scientific research shall be free of constraint. Framed like this, 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>24</sup>

### **3.2 *International Administrative Regulation***

At the level of fundamental rights, there are hardly any international or European sources containing binding administrative rules concerning cross-border biobanking directly.<sup>25</sup> EU law contains secondary legislation that may be applied in connection to biobanking (3.2.1). Instead, the main source consists of soft law (3.2.3).

#### **3.2.1 *Secondary EU Law***

Within the EU, there is some secondary legislation 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 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

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23 Lind, A.-S., *The Right to Health from a Constitutional Perspective – the Example of the Nordic Countries*, in: Rynning & Hartlev (eds.), *Nordic Health Law in a European Context*, Martinus Nijhoff Publishers, 2011, pp. 67–76.

24 Ruffert & Steinecke, op cite, note 3, p. 31.

25 Rynning, op cite, note 3, p. 301.

ethical issues directly.<sup>26</sup> Further, it has proven difficult for the Member States to reach workable agreements on issues affecting ethical or moral issues, as shown by for example the “moral clause” in the Biopatent Directive,<sup>27</sup> and the legal framework concerning genetically modified organisms (GMO).<sup>28</sup>

EU law does however contain two secondary legislative acts relevant to the area of bioethics, if not directly regulating it, the Data Protection Directive<sup>29</sup> and the above-mentioned Biopatent Directive.<sup>30</sup> The Data Protection Directive, currently undergoing revision,<sup>31</sup> has the dual aim of protecting the free flow of personal data between Member States at the same time as 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 Data Protection Directive in reality is highly relevant. The impact of the Directive is discussed further below in section 3.3. Other regulatory measures also affect this area indirectly, such as the decision on the Seventh Frame Work Programs for research, where it is stated that all research shall be carried out in compliance with fundamental ethical principles.<sup>32</sup> According to

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26 *See*, for example, Amended Proposal for a Directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells COM(2003) 340 final, p. 4, where the Commission rejects certain proposals from the European Parliaments on ethical issues, on the grounds that Article 168 TFEU [at the time, Article 152 EC] does not give the EU competence in that field. *See* further, Busby, H., *Ethical EU Law? The Influence of the European Group on Ethics in Science and New Technologies*, *European Law Review*, 2008, (33(6)).pp. 803–842, p. 820.

27 Article 6 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. The Directive has been the object for an extensive legal debate, *See* for example several contributions in Plomer, A. & Torremans, P. (eds), *Embryonic Stem Cell Patents*. *European Law and Ethics*, Oxford University Press, 2009, as well as judicial proceedings before the Court of Justice of the European Union (CJEU), C-377/98, *Netherlands v European Parliament and Council*, ECR 2001, p. I-7079 and more recently, Case C-34/10, *Oliver Brüstle v Greenpeace e.V.*, ECR 2011, not yet reported.

28 For example, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms. This directive has also been the target of academic debate, *See* for example, Krisch, N., *The Pluralism of Global Administrative law*, *The European Journal of International Law*, vol 17 no. 1, pp. 247–278, p. 256 ff, as well as judicial proceedings, C-165/08 *Commission v. Poland*, ECR 2009, p. I-6843.

29 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.

30 Rynning, *op cite*, note 22, p. 305.

31 Commission proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), COM (2012)11 final.

32 Decision 1982/2006 concerning the Seventh Framework Program of the European Community for research, technological development and demonstration activities (2007-2013) [2006] OJ L412/1.) *See* further Busby, *op cite*, p. 833.

the preamble of this decision, the opinions of the EGE will be taken into account.<sup>33</sup>

### 3.2.2 Soft Law

The main source for administrative practices in the area of ethics in international biobanking is soft law, as issued by international organisations 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. 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>34</sup>

An abundance of documents of different sorts exists at the international level in the area of bioethics. Apart from the declarations on human rights as mentioned above in section 3.1, the WHO has also issued a ‘Guideline for obtaining informed consent for the procurement and use of human tissues, cells and fluids in research’. In Collaboration with CIOMS,<sup>35</sup> WHO has further issued two guidelines, International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002, and International Ethical Guidelines for Epidemiological Studies, 2008. The Council of Europe has issued an additional protocol and an explanatory memorandum to the protocol of the above-mentioned Convention on biomedicine,<sup>36</sup> as well as recommendations that may be relevant to biobanking.<sup>37</sup> The World Medical Association (WMA), an independent confederation of free professional associations for physicians, has enacted several different declarations,<sup>38</sup> of

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33 Paragraph 33 of the preamble to the decision. See further, Plomer, A, *The European Group on Ethics: Law, Politics and Limits of Moral Integration in Europe*, European Law Journal Vol. 14, Issue 6, 2008, pp. 839–859, p. 847.

34 Ruffert & Steinecke, op cite, note 3, p. 115.

35 Council for International Organizations of Medical Science.

36 Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasbourg, 2005 and Council of Europe Committee of Ministers, Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research.

37 For example Recommendation on research on biological materials of human origin adopted by the Committee of Ministers of the Council of Europe and Recommendation No R(99)4 of the Committee of Ministers to member States on principles concerning the legal protection of incapable adults.

38 WMA Declaration on the Rights of the Patient, 1981, WMA Statement on Patient Advocacy and Confidentiality, 2003, WMA Declaration on Ethical Consideration Regarding Health Databases, 2002, WMA Statement Concerning The Relationship Between Physicians and Commercial Enterprises, 2004 and WMA Statement on Genetics and Medicine, 2005.

which the Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects is the most important.<sup>39</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>40</sup> The latter advisory group is connected to the Data Protection Directive, and specializes on questions regarding personal data protection.

Further, the EU also acts as a supranational organisation in the international field of research.<sup>41</sup> Since the entering into force of the Lisbon treaty in 2009, the competence of EU within this field has been 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>42</sup> In the 2020 Strategy, the EU has defined several steps for achieving a sustainable economy and growth in Europe.<sup>43</sup> One part of the strategy is directed at research and innovations. In line with this work, the EU has introduced several agencies, programs and instruments to facilitate research, even prior to the Lisbon Treaty. One is the European Strategy Forum on Research Infrastructures (EFRSI), a Commission-instrument to support a coherent and strategic policy for research infrastructures in Europe.<sup>44</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>45</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>46</sup> Even though the research projects within the BBMRI cannot produce authoritative statements of the law, this work is an illustrative example of the needs of researchers for guidance in applying the rather obscure regulatory regimes applicable to cross-border biobanking. And, in an area

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39 See further the website of the World Medical Association at [www.wma.net](http://www.wma.net).

40 See, for example, Article 29 Data Protection Working Party, Working Document on Genetic Data, 12178/03/EN, 2004 and EGE Opinion no. 15 on Ethical Aspects of Human Stem Cell Research and Use.

41 Ruffert & Steinecke, *op cite*, note 3, p 65.

42 Article 179 TFEU.

43 Communication from the Commission, Europe 2020 A strategy for smart, sustainable and inclusive growth COM(2010) 2020 final.

44 Available at the EU website: “[ec.europa.eu/research/infrastructures/index\\_en.cfm?pg=esfri](http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=esfri)” See further, Beijer, M., *Soft law i EU – Dess roll inom området för bioetik i EU och BBMRI*, FT 2012, pp. 135-148.

45 BBMRI.eu. The research for this article has been funded by BBMRI.se, the Swedish part of the infrastructure.

46 Available via BBMRI.eu or directly “[www.legalpathways.eu/index.php?option=com\\_joomlawiki](http://www.legalpathways.eu/index.php?option=com_joomlawiki)”, accessed the 10 of May 2012. The research project is currently not active, but there are similar projects running within the BBMRI.se.

where common binding international rules are few, but soft law is plenty, standard-setting activities among a large group of researchers may in the long run have some normative effect.<sup>47</sup>

### **3.3 National Law and Common Principles in its Application**

As a general point of departure, 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>48</sup> In the OECD guidelines on human biobanks and genetic research databases (HBGRD) the use of an independent research ethics committee as one of the main prerequisite of best practices.<sup>49</sup>

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.

Ruffert and Steinecke maintain that these types of committees exist in almost all countries.<sup>50</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. Standardised 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>51</sup> the biobanks themselves<sup>52</sup>, or, as discussed above, provided by groups of researchers.<sup>53</sup>

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

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47 Compare Ruffert & Steinecke, op cite, note 3, p 115.

48 See, for example, the CIOMS/WHO International Ethical Guidelines for Epidemiological Studies, guideline 2, International Ethical Guidelines for Biomedical Research Involving Human Subjects, p. 24, Article 9 of the Council of Europe Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasbourg, Articles 15, 25 and 29 of the WMA Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects.

49 Paragraph 1.2 of the guidelines.

50 Ruffert & Steinecke, op cite, note 3, p. 98.

51 See, for example, in Sweden, the National Biobank Council, consisting of representations from regional municipalities (health care principal), universities and pharmaceutical industries, provides various model forms on its website: "www.biobanksverige.se".

52 See, for example, the UK biobank's website, "www.ukbiobank.ac.uk".

53 See above regarding BBMRI.eu, "www.legalpathways.eu".

above, no globally applicable administrative rules. As pointed out in the introduction, one and the same research project collecting samples from several states must therefore seek approval from committees in every state.<sup>54</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>55</sup> The transfer must usually be preceded by entering into an agreement between the sender and receiver, a material transfer agreement (MTA). All the conditions for handling the samples are regulated in the MTA, specific restrictions regarding the given consent, etc. Standardized forms for MTAs are often made available by the same actors providing forms for informed consent.

The transfer of personal data is regulated by the above-mentioned Data Protection Directive within the EU. The Directive 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>56</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>57</sup> The 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 Directive.<sup>58</sup> In such cases, personal data may be transferred to these countries on the same conditions as within the EU.

Second, the Commission may conclude Safe Harbor agreements, allowing transfers of data to specific entities within a state adhering to the principles laid down in the agreement. This has been done vis-à-vis the USA, for example.<sup>59</sup> If none of these options are available, the third option is to enter into an agreement with the receiving party. The Commission has enacted standard contractual clauses, containing the necessary set of information to enter into an

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54 See for a discussion of the issue, *See* Hansson MG, Gattorno M, Forsberg JS, Feltelius N, Martini A, Ruperto N., Ethics bureaucracy: a significant hurdle for collaborative follow-up of drug effectiveness in rare childhood diseases, *Arch Dis Child*. 2012 June;97(6):561-3.

55 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. *See* for a description of Swedish law, the website of the Swedish Biobank available at "www.biobanksverige.se".

56 *See* Article 8 of the Data Protection Directive.

57 *See* Article 25.1 of the Data Protection Directive.

58 *See* Article 25.5-6 of the Data Protection Directive. The list of countries that has been found to have an adequate level of protection can be found on the EU website at "ec.europa.eu/justice/data-protection/document/international-transfers/adequacy/index\_en.htm".

59 Commission decision C(2000) 2441 pursuant to Directive 95/46/EC of the European Parliament and of the Council on the adequacy of the protection provided by the Safe Harbor Privacy. Principles and related Frequently Asked Questions issued by the US Department of Commerce.

agreement to transfer personal data outside the EU.<sup>60</sup> These agreements are equivalent to the above-mentioned MTAs and are usually referred to as data transfer agreements (DTA). As stated in its preamble to the decision, the use of the standard contract is voluntary as the clauses are only one of several possibilities under the Data Protection Directive.<sup>61</sup> However, since there are a number of competing, and to some extent divergent, standard contractual clauses available,<sup>62</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.

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.

#### 4 Analysis

As seen above, 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. Hereby 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. As stated by 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 therefor entails less of a commitment for the involved states.<sup>63</sup> 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 standardised forms for collecting consents

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60 Commission Decision 2004/915/EC of 27 December 2004 amending Decision 2001/497/EC as regards the introduction of an alternative set of standard contractual clauses for the transfer of personal data to third countries OJ L 385 pp. 74 – 84.

61 Paragraph 3.

62 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), footnote 3.

63 Spina, A., *The Regulation of Pharmaceuticals beyond the State*, Chiti, E & Giorgio Mattarella, B (Eds), *Global Administrative Law and EU Administrative Law. Relationships, Legal Issues and Comparison*, Springer, Berlin Heidelberg, 201, p. 2611.

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 of the current as well as possible 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 regimes of low hierarchical legal value, the use standardised forms drafted by low-level administrative or hybrid private-public organs, reviewed by similar types of organs, 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 indirectly – the 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 globalised 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>64</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>65</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 in fitting into the ethical regulatory framework, even on a national level.

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64 Krisch, *op cite*, note 28, p. 267, von Bogdandy, A., *Pluralism, direct effect, and the ultimate say: On the relationship between international and domestic constitutional law*, *International Journal of Constitutional Law*, vol 6 No. 3 & 4, 2008, pp. 397–413, p. 412 and Reichel, J., *European Legal Method from a Swedish Perspective - Rights, Compensation and the Role of the Courts* Nielsen, R., Neergaard, U. & Roseberry, L. (eds), *European Legal Method*, DJØF Publishing Copenhagen, 2011, p. 267.

65 Cassese, *op cite*, note 9, p. 669 and Zamboni, M., *Globalization and Law-making: Time to Shift a Legal Theory's Paradigm*, *Legisprudence. International Journal for the Study of Legislation* 1/1, pp. 125-153 (2007), p. 142.

O'Doherty *et al.* argue that 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. 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>66</sup> In Sweden, one of the largest research projects funded by the Swedish Research Council, LifeGene, was stopped by the Swedish Data Inspection Board in December 2011, due to this very reason.<sup>67</sup>

The way forward suggested by O'Doherty *et al.* is to focus on innovative governance and engagement strategies in order not to be held captive by a "contractual interpretation of informed consent documents".<sup>68</sup> These authors include representativeness, accountability, transparency, reflective practice and sustainability as necessary conditions for trustworthy biobank governance.<sup>69</sup> Within the EU, an expert group under the Commission has also recently published a report focusing on governance strategies for biobanks.<sup>70</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>71</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 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>72</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 Harlow

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66 O'Doherty, K.C., Burgess, M. M., Edwards, K. Gallagher, R. P., Hawkins, A.K., Kaye, J., McCaffrey, V., Winickoff, D. E., *From consent to institutions: Designing adaptive governance for genomic biobanks*, *Social Science & Medicine* Vol. 73, Issue 3, August 2011, pp. 367-374, p. 367 and Hansson M.G., Dillner J, Bartram C.R., Carlsson J., Helgesson G., *Should donors be allowed to give broad consent to future biobank research?*, *The Lancet Oncology*, 2006;7:266-269.

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

68 O'Doherty et al, op cite, note 66, p. 369.

69 Ibid.

70 *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.

71 Hansson MG, et al, op cite, note 54.

72 Chiti, E, *EU and Global Administrative Organizations*, Chiti, E. & Giorgio Mattarella, B. (eds), *Global Administrative Law and EU Administrative Law. Relationships, Legal Issues and Comparison*, Springer, Berlin Heidelberg, 2011, p. 16.

(the other being democracy).<sup>73</sup> The problem, according to Harlow, seems less connected to the application of principles, but rather to the structures of legal globalisation; ‘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>74</sup>

Perhaps the idea of basic administrative procedural safeguards, developed in administrative procedures at the global level, however vague, can 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>75</sup> Even if the situation in the *Kadi*-case 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 globalisation,<sup>76</sup> and there is no reason to believe other than that it may also be relevant in the area of bioethics. A point of relevance to this end is raised by Plomer, the need to scrutinize the appointments of members of influential ethical groups, such as the EGE in the EU.<sup>77</sup>

In my opinion, 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 and distinguish which sources are relevant to whom and when among the vast supply of global guidelines, standardised forms and contractual clauses. 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 as a bit contradictory to state

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73 Harlow, op cite, note 9, p. 190 and section 2.2 above. See further Palombella, op cite.

74 Harlow, op cite, note 9, p. 212.

75 Case C-402/05 P *Kadi and Al Barakaat International Foundation v. Council and Commission* ECR 2008, p. I -6351, paras. 334 and 348.

76 Mendes, J., *Administrative Law Beyond the State: Participation at the Intersection of Legal Systems*, Chiti, E & Giorgio Mattarella, B (Eds), *Global Administrative Law and EU Administrative Law. Relationships, Legal Issues and Comparison*, Springer, Berlin Heidelberg, 2011.

77 Plomer, op cite, note 33, p. 858.

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 present, the categorical distinction between “binding” and “non-binding” loses its overall importance.<sup>78</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 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.<sup>79</sup>

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78 Ruffert & Steinecke, op cite, note 3, p. 114.

79 Harlow, C. & Rawlings, R., *Promoting Accountability in Multilevel Governance: A Network Approach*, *European Law Journal*, Vol 13 No. 4, 2007 p. 542-562.