International Law from a Baltic Perspective

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The Regulation of Research on the New Biomedical Technologies: Standard Setting in Europe and its Baltic Region

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1 Introduction*

Rapid development is taking place in the fields of biology and medicine in Europe and worldwide. Biology and medicine have offered, and will continue to offer, much to our European and global societies, but these contributions and their attendant risks do not exist in a vacuum. While offering great promise for the future, this development has ethical, legal, and social ramifications that cannot be ignored. Genomics, embryo research, and the field of biomedical research in general raise both hopes and concerns as the attention of the media and our democratic institutions turns to the societal fallout of recent discoveries.

A theme underlying this article is whether we have an actual or potential conflict between 'economism' and human rights in the domain of the new biomedical technologies. Some current developments in the Baltic countries will

* The views expressed are personal and do not necessarily reflect any official position of the Council of Europe.

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be examined specifically,[1] but this is a topical issue elsewhere in Europe and globally.[2] The response of the European institutions to developments in these fields and the guidance offered to States wishing to enjoy orderly progress in the achievement of better health and economic development will be reviewed. The main focus will be on the system of a Convention and Protocols elaborated by the Council of Europe because of its leading role in bioethics and its focus on human rights, dating back to the *European Convention for the Protection of Human Rights and Fundamental Freedoms* (*European Convention on Human Rights*) in 1950. I will put forward the proposition that observance of human rights, particularly in this field, is necessary to ensure sustainable and orderly economic development in a knowledge economy. Therefore, while strictly economic factors are important they should not be seen as the only determinant in setting policy.

At the same time, it is necessary to acknowledge that the contributions of European Union institutions are also quite relevant, particularly in the context of European Union enlargement in the Baltic region. The Community is empowered to act in this field on the basis of EC Treaty Articles 152 (public health), Articles 163 to 173 (research, funding of the research framework programme), and 95 (the internal market). Additionally, Article 49 of the Treaty of the European Union states that candidate countries must respect human rights and fundamental freedoms in order to join the European Union. Direct reference is made in Article 6 of the *Treaty of the European Union* to the *European Convention on Human Rights*.

Not least of all as a major funding source for research in Europe, the European Commission has direct influence on what is considered ethically acceptable for researchers. In the field of pharmaceutical research, Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practise in the conduct of clinical trials on medicinal products for human use was adopted on 4 April 2001.

It is important to note that the instruments of the Council of Europe and the European Union do not cover identical fields. Set up in 1949, the Council of Europe is an intergovernmental organisation with a pan-European vocation

1 A controversial aspect of the draft Latvian law on Research on the Human Genome has been the possibility of private investment in the Genome database. Baltic News Service, "*Iebilst pret genoma datu bāzi privātās rokās*" <www.delfi.lv> accessed on 18 July 2001.

2 One of the liveliest bioethics debates has been going on in the United States in regard to federal financing for, and regulation, of stem cell research. See Sh. G. Stolberg, "Key Bush Ally Backs Studies of Stem Cells, With Limits", <www.nytimes.com> accessed on 19 July 2001. Discussion and regulation has also been taking place on the state level. See Sh. G. Stolberg, "Washington Not Alone in Cell Debate", <www.nytimes.com> accessed on 23 July 2001.

that fosters political, legal and cultural co-operation between its 43 member European pluralistic democracies.[3] It is quite distinct from the 15 Nation European Union, though all of the European Union member countries are also members of the Council of Europe. The aims of the Council of Europe, as specified by its Statute, are to protect human rights and strengthen pluralist democracy, to enhance European cultural identity and seek out solutions to the major problems of our time such as the bioethical problems addressed by the *Convention on Human Rights and Biomedicine.* The Secretary General of the Council of Europe, Mr. Walter Schwimmer, noted in his speech on the role and place of the Council of Europe in the context of the enlargement of the European Union at the Paris Press Club on 3 July 2001 that the problems of bioethics are not limited to just one part of Europe.[4]

The Council of Europe operates through two principal bodies, the Committee of Ministers, its decision-making body and the Parliamentary Assembly, its deliberative body. A Secretariat General serves these bodies and is headed by a Secretary-General elected for five years. The most tangible results of intergovernmental cooperation in the Council are European conventions, drawn up as a contract between signatory States. Each State accepts a number of obligations in return for acceptance of the same obligations by other States. It is necessary to stress that that the treaties are not legal instruments of the Council of Europe as such, but owe their existence to the Member States that sign and ratify them. Even though the treaties have a life of their own, they are in many cases followed by expert committees set up within the Council of Europe.[5] The

3 The Statute on the Council of Europe emerged from the 'Congress of Europe' which was convened at The Hague on 7 May 1948 to draw up proposals for European unity in the aftermath of World War II. The Congress revealed the differences in opinion between those who were unconditional supporters of a European federation from those who favoured simple inter-governmental co-operation. See P. Craig and G. De Burca, *EU Law, Text, Cases and Materials,* 2nd ed., (Oxford, 1980), p.8; see also, P. Kapteyn and P. VerLoren van Themaat, *Introduction to the Law of the European Communities,* 2nd ed., (Kluwer, 1989), p.3. On 27 and 28 January 1949, the five Ministers of foreign affairs of the Brussels Treaty countries reached a compromise: a Council of Europe consisting of a ministerial committee, to meet in private; and a consultative body to meet in public. In order to satisfy the countries supporting co-operation, the Assembly was purely consultative in nature, with decision-making powers vested in the Committee of Ministers. On 5 May 1949, the Treaty constituting the Statute of the Council of Europe was signed by ten countries in London, U.K. See <www.coe.int> "A short history".

4 <http://test.press.coe.int/Discours/Wspressclub-e.htm> accessed on 30 April 2020.

5 J. Polakiewicz, *Treaty-Making in the Council of Europe* (Council of Europe Publishing, 1999), p. 10.

Council of Europe has drawn up more than 170 multilateral conventions,[6] including the *European Convention on Human Rights.*

While the Council of Europe's *Convention on Human Rights and Biomedicine* covers all types of biomedical research on human beings, the aforementioned European Union Directive on good clinical practise deals only with pharmaceutical research. In regard to medicinal products, it has been stated that the 'European Community has a clearly established legal competency. The legal basis for Community action is the principle of the free movement of goods in the European Union embodied in Article 3 of the Treaty of the European Union'.[7] However, it has also been commented that the European Union Directive 'will have a wider impact than just the pharmaceutical area alone. These changes in the national legislation will likely cover the whole scope of clinical research, not simply pharmaceutical research'.[8] In any case, the two institutions have cooperated in this field and most likely will continue such mutually beneficial cooperation in the future.

To some extent, this analysis will be based on draft instruments both at the international and national level. Therefore, it is necessary to keep in mind that the instruments referred to may be adopted in a modified form in the end. However, in this rapidly changing domain this may prove to be beneficial to readers utilizing this analysis in several years time or later. One of the premises of this article is that the instruments being developed by the European institutions in the field of the new biomedical technologies are proving to be influential in setting standards for biomedical research in the Baltic countries, and that their participation in the debate of these instruments and receptiveness to the results of this debate have influenced their own legislation. Additionally, these instruments are a reflection of the thinking at the intergovernmental and national levels on these subjects in 2001–2002 when the debate of these issues continued to grow in intensity and reach (moving into the mass media).

Promotion of private enterprise and the protection of human rights do not need to be polar opposites, as they are not in the democratic and free-market based Member States of the Council of Europe and European Union. The importance of individual liberty in the sphere of commerce must not be underestimated. However, new questions arise in the domain of biomedicine as new

6 Further information on the Conventions and agreements in the European Treaty Series (ETS) can be found in English or French at <http://conventions.coe.int/treaty/EN/Menuprincipal.htm>.

7 See L. Cordier, "Is there a European ethical framework for clinical research?" (1997) 11 *International Journal of Pharmaceutical Medicine,* pp. 137–140.

8 *Ibid.*

developments challenge the roles of the individual, the family, the doctor, and the health care worker. Is it sufficient to take a strict *laissez-faire* approach and say, 'if something is technically feasible and there is enough money behind it, then it will be done?' This type of approach could be described as a narrow 'economism', where economic growth is treated as a kind of a god with priority over all other considerations.[9] While we need not find any conflict between the promotion of private enterprise and the protection of human rights, we will have a conflict if economic and entrepreneurial considerations overshadow the ethical, social and legal aspects surrounding research and application of new biomedical technologies.

A counterproposal to the 'full speed ahead' approach is the use of the precautionary principle by decision makers.[10] The European Group on Ethics in Science and New Technologies (EGE) has stated that the precautionary principle, being the expression of prudence as a genuine ethical virtue, is applicable especially to the new technologies.

Of course, there are other valid arguments that might be called upon in order to support a specific undertaking in biomedical research such as the freedom of research and the possibility to help those suffering from disease. Fears may arise that if a type of research is prohibited in a single country, it will fall behind in the progress of its research and become dependent on work done elsewhere.[11] These considerations must also be taken into account by those making ethical and legal evaluations of a direction in research or a specific project. However, it often seems that if the profit motive is present it is most suspect to members of the public. Potential conflicts between advocates of economic growth and human rights can be seen today in relation to cloning, embryo research and research on the human genome.

1.1 *Developments in Europe at the National Level*

In the field of genetic research, Iceland's *Database Act* has allowed the creation and operation of a health records database intended to contain records of the population with the possibility of cross-linking the health data to genetic data and genealogical information. The Icelandic initiative took the lead in establishing this type of linked database, but it has not been without controversy.

9 L. Siedentop, *Democracy in Europe* (London: The Penguin Press, 2000), p. 33.

10 B. Charles and A. Claeys, "Réviser les lois bioéthiques: quel encadrement pour une recherche et des pratiques médicales maîtrisées?", *Les documents d'information de l'Assemblée Nationale,* No. 3208, 2001, pp. 16–17.

11 B. Charles and A. Claeys, "Réviser les lois bioéthiques: quel encadrement pour une recherche et des pratiques médicales maîtrisées?", *Les documents d'information de l'Assemblée Nationale,* No. 3208, 2001, pp. 27–28.

Opponents have pointed to the use of presumed consent for inclusion of personal data in the health records database as being a fundamental shortcoming. The commercial connotations of the database have also raised concern among many observers worried about the role of 'big pharma' and the monopolisation of the population's health records. It is notable that both aspects of the Icelandic experience have been evaluated positively and negatively and have served as examples elsewhere in Northern Europe, specifically in Estonia and Latvia.

In Estonia, the Estonian Genome Project Foundation, established on the basis of the *Human Genes Research Act* of 8 January 2001, opted for explicit consent (as required in the Council of Europe and European Union instruments) rather than the aforementioned presumed consent model. As Ants Nomper discusses this Act in detail in another article in this Yearbook, I will refrain from further comment on the Estonian legislative initiative. In any case, it will be interesting to follow the implementation of the Act and Project in 2002 and beyond.

On 26 June 2001, the Latvian Parliament (*Saeima*) submitted the *Draft Law on Research on the Human Genome* to the Parliamentary Commissions for review prior to its presentation to the plenary. It was expected that the Draft Law would be discussed in plenary in fall 2001. The Draft Law aimed, first and foremost, to guarantee the free consent of the donors to their participation in genome research, as well as to the extent of said participation. The authors of the draft Law stated they placed emphasis on the human rights aspect of this requirement. Secondly, the authors wished it to guarantee the confidentiality of the stored data and the anonymity of the donors. They foresaw a State institution that would act as the central mechanism for the coordination of the programme as well as the guarantor of the confidentiality of the data/biological materials utilised therein. Finally, their aim was to regulate the collection and storage of genetic information, and to ensure State supervision of these processes. The authors foresaw that the 'anonymised' genetic information could be used by institutes and by companies in the fields of biotechnology, pharmaceuticals, data processing and information technology, ensuring that a monopoly would not arise.[12]

In a closely related development, the enterprise GENDB S.I.A. (Ltd.) was registered in Latvia's Enterprise Register at the end of June 2001. The main aim of the enterprise was to attract private capital to the State project for the development of a Latvian genome database. It was hoped that State financing would be foreseen in the 2002 budget.

12 R. Ražuks, "Vai mums jābaidās no saviem gēniem?", <www.diena.lv/> accessed on 27 June 2001.

2 Instruments of the Council of Europe

Returning to the discussion on the European level, the approach of the Council of Europe to these issues is based on human dignity; the equal dignity of all human beings being the essential foundation of all philosophy and law of human rights. Human dignity must be maintained and protected while welcoming the ethical scientific advances that can cure disease and help members of our society lead healthier and happier lives. The mission of the Council of Europe in bioethics has been interpreted as: (1) offering a forum for reflection and debate; (2) acting as watchdog for fundamental values; and (3) arbitrating, with reference to those fundamental ideals, between the different points of view and the different interests at stake and, accordingly, to develop principles and rules of law to be observed and applied by all.

The Convention on Human Rights and Biomedicine is the first international agreement on the new biomedical technologies. Its full title is the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. It was opened for signature on 4 April 1997 in Oviedo, Spain and 30 countries[13] have signed to date. It is expected that other States will be signing, and ratifying, the Convention in the future. In addition to the Member States of the Council of Europe, the following States, which took part in the preparation of the Convention may sign: Australia, Canada, the Holy See, Japan and the United States of America.

In addition to the *Convention on Human Rights and Biomedicine* and its Protocol, the result of the Council's work in bioethics is an important normative corpus relevant to bioethics issues such as, the protection of human embryos and foetuses, developments in biotechnology and agriculture, legal protection of persons suffering from mental disorder placed as involuntary patients, medical research on human beings, and genetic testing and screening for health care purposes.

Thus, the Council seeks to cooperate with other concerned European and international institutions and organisations to ensure that such an ethical and legal infra-structure continues to develop and that it reflects the principles and philosophy of our European democratic heritage. The first step in reaching

13 As of 1 October 2001: Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Moldova, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, The Former Yugoslav Republic of Macedonia, and Turkey.

consensus must be dialogue. It is in the interest of all that ideas are freely exchanged and issues discussed openly.

For the first time, the Convention seeks to establish a common, minimum level of such protections throughout Europe. Finding a consensus on such a minimum level was not a simple task. The traditions and approaches of some countries favoured an approach of stringent prohibitions in some spheres. Other countries were of the opinion that some prohibitions could be seen as paternalistic, and could take away the choice of an individual, as well as the opportunity of the individual to receive some benefit of biomedicine. A balance also needed to be found between the freedom of research, which brings many benefits to individuals suffering from diseases, and the regulation of research to protect the same or different individuals.

Of course, some countries may wish to offer now or in the future a yet higher standard of protection in some sphere of biomedicine. The Convention was drafted with such a possibility in mind. Article 27 (Wider protection) states that none of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention. The Convention is structured so as to set out only the important principles in order to provide a common framework for the protection of human rights and human dignity in both longstanding and currently developing areas concerning the application of biology and medicine. It was decided that additional standards and more detailed questions would be dealt with in five additional protocols.

The Convention and its Protocols are a 'system' that can respond to new (and sometimes threatening) developments in biomedicine. An example is the preparation of the Protocol prohibiting human cloning after the news of Dolly's birth came out. Another example is the provision of the draft Protocol on Biomedical Research addressing research in non-Party States, which was developed in response to allegations of exploitation of research subjects from the South and Central and Eastern Europe by 'western' researchers.

Ten Member States have ratified and the Convention has come into force for these countries.[14] The Convention first came into force on 1 December 1999. It is up to the countries signing and ratifying the Convention to give effect to its provisions in their national legislation. This process is followed up by the Secretariat and the Steering Committee on Bioethics (CDBI) at the Council of

14 Czech Republic, Denmark, Georgia, Greece, Portugal, Romania, San Marino, Slovak Republic, Slovenia and Spain.

Europe. Assistance is provided to signatories to adapt their institutions and legislation to the requirements of the Convention.

The Convention's roots can be traced to the 17th Conference of the European Ministers of Justice (Istanbul, Turkey, 5–7 June 1990), who adopted Resolution no. 3 on bioethics which recommended that the Committee of Ministers instruct the CAHBI to examine the possibility of preparing a framework convention 'setting out common general standards for the protection of the human person[15] in the context of the development of the biomedical sciences'. The Resolution was based on a proposal by Ms. Catherine Lalumiere, Secretary General of the Council of Europe at that time. The Parliamentary Assembly of the Council of Europe recommended in June 1991, in its Recommendation 1160, that the Committee of Ministers 'envisage a framework convention comprising a main text with general principles and additional protocols on specific aspects'. We see that this approach based on a framework convention with specific protocols was the one that was eventually adopted. The support for the proposal continued to grow when in September 1991, the Committee of Ministers instructed the CAHBI to prepare a framework convention setting out common general standards for the protection of the human person in the context of the biomedical sciences and alluded to protocols to this convention on organ transplants and the use of substances of human origin, and on biomedical research.

In March 1992, the CAHBI formed a Working Party to prepare the Draft Convention. In July 1994, a first version of the Draft Convention was opened for public consultation and was submitted to the Parliamentary Assembly for an opinion.[16] The CDBI, which had replaced the CAHBI, took this opinion and others into account in preparing a final draft. The CDBI confirmed this Draft on 7 June 1996 and submitted to the Parliamentary Assembly for an opinion.[17] The Committee of Ministers adopted the Convention on 19 November 1996.[18]

2.1 *Requirements of the Convention on Human Rights and Biomedicine*

The Convention gives precedence to the human being over the sole interest of science or society. The aim of the Convention is to protect human rights and

15 It is interesting to note that the term 'human person', utilised in a number of documents proposing the preparation of the Convention, does not appear in the Convention itself. The Convention utilises 'everyone', 'human being' or 'person'.

16 Opinion No. 184 of 2 February 1995, Doc. 7210.

17 Opinion No. 198 of 26 September 1996, Doc. 7622.

18 Germany and Belgium requested that their abstention when the Committee of Ministers voted on the adoption of the Convention and the authorisation of publication of the explanatory report be recorded.

dignity and all of its articles must be interpreted in this light. The main focus of the Convention in regard to biomedical research is specifically this human rights aspect, unlike other legal instruments in the field, which may concentrate, for example, to a large extent on the economic, and public health aspects of making new medicines available more quickly. The interests of society and science are not neglected however and come immediately after those of the individual. On this basis, it establishes that consent is obligatory for any medical treatment or research and recognises the right of all individuals to have access to information concerning their health. The text also sets out safeguards protecting anyone, of any age, who is unable to give consent.

The term 'Human Rights' as used in the title and text of the Convention refers to the principles found in the *European Convention on Human Rights* of 4 November 1950, which guarantees the protection of such rights. The *Convention on Human Rights and Biomedicine* not only shares the same underlying approach, many ethical principles and legal concepts, but also elaborates on some of the principles found in that Convention. Additionally, Preamble to the Convention acknowledges the fundamental nature of the principles of human rights enshrined in the *Universal Declaration of Human Rights,* the *International Covenant on Civil and Political Rights,* the *International Covenant on Economic, Social, and Cultural Rights,* the *Convention on the Rights of the Child,* the *European Social Charter,* and, in a more specific instrument, the *European Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data.* This Convention builds on the principles embodied in these instruments to ensure the protection of human rights in the context of the recent advances in biology and medicine.

The Convention contains two types of provisions. The first part of the Convention is a codification of the principles of modern medical law in regard to information and consent and to the protection of those unable to consent. The second part contains the provisions addressing biomedical research and the new biomedical technologies. These issues are to be addressed in the additional Protocols to the Convention.

Five additional Protocols have been proposed to supplement the Convention. The Protocols are designed to address the ethical and legal issues raised by present or future scientific advances through the further development, in specific fields, of the principles contained in the Convention. The additional *Protocol on the Prohibition of Cloning Human Beings* and the *Draft Additional Protocol on Transplantation of Organs and Tissues of Human Origin* are completed to date. The *Draft Protocol on Biomedical Research* was declassified for consultation purposes in June 2001. Any State that is a signatory to the Convention is able to sign a Protocol.

The Draft Additional Protocols on protection of the foetus and the human embryo, and on human genetics are currently being drafted by working parties made up of high level experts nominated by Council of Europe Member States with the assistance of the Secretariat of the Council of Europe (the Bioethics Division in the Directorate General – Legal Affairs). The high level experts take into account the views of non-governmental and professional organisations active in the respective fields in the preparation of the Protocols. This is done through consultations with such organisations between meetings and through consultations with European-wide bodies arranged in Strasbourg during the meetings of the working parties. The working parties also consult with other regional and international bodies that are working with related issues.

Returning to the Convention itself, Article 1 sets out its purpose and object, this being the protection of the dignity and identity of all human beings and the guarantee, without discrimination, for everyone of respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. The drafters preferred the phrase 'application of biology and medicine' to that of 'life sciences', in particular, as they wished to exclude animal and plant biology from the scope of the Convention.

Article 2 establishes the primacy of the human being over the sole interest of society or science. Article 3 (Equitable access to health care) states that Parties shall take appropriate measures with a view to providing equitable access to health care of appropriate quality within their jurisdictions. It is important to note that this requirement is qualified by the following statement: 'taking into account health needs and available resources'. Parties will have to set priorities for their healthcare expenditures themselves and the drafters fully realised that there is a wide income disparity between the most developed and less developed Council of Europe Member States, thereby rendering any attempt at setting some prescribed level of healthcare unsuccessful. The Article requires that access to health care be equitable. The Explanatory Report to the Convention notes that in this context, 'equitable' means first and foremost the absence of unjustified discrimination. Although not synonymous with absolute equality, equitable access would imply effectively obtaining a satisfactory degree of healthcare.

Article 4 (professional standards) of the Convention requires that any intervention in the health field, including research, must be carried out in accordance with the relevant professional obligations and standards. The term 'intervention' is used here in a broad sense covering all medical activities directed at human beings for preventive care, diagnosis, treatment, rehabilitation, or research. The Article covers both written and unwritten rules.

The Convention clearly states the general rule that an intervention in the health field may only be carried out after the patient has given free and informed consent to it (Article 5). Consent may be looked at in the ethical sense as a critical component of the relationship between a physician and his patient within the context of medical, ethical, and professional standards that the medical professional has sworn to uphold, while in the legal sense it can extend to liability for the physician who does not fulfil the necessary steps of obtaining consent.

Freedom of consent implies that consent may be withdrawn at any time, but does not mean that the withdrawal of consent during an operation, for example, must always be honoured if such an obligation would be contrary to the professional standards and obligations which the physicians must uphold.

The Convention also provides safeguards for persons not able to consent (Article 6). According to Article 6, intervention is permitted only for the direct benefit of persons. Where a minor is involved, any intervention must be authorised by the person or body responsible by law for the minor. Also, the opinion of a minor may be considered and is increasingly recognised as a determining factor in proportion to the minor's age and degree of maturity.

Moreover, it is important to note that a parent, for example, has responsibility for a child, not power over that child. This means that the parent must always act in the interests of the child and must ensure that the decisions taken further the well-being and health of the child. Physicians and other health care professionals, under their professional standards, must also act in the interests of the patient (the child in this case).

The Article 6 requirement is subject to the provisions of Articles 17 (protection of persons undergoing research) and Article 20 (protection of persons not able to consent to organ removal). The exceptions to Article 6 in these two contexts are addressed below.

Chapter III and Article 10 deal with private life[19] and the right to information. Article 10 sets out the principle that everyone has the right to respect for private life in relation to information about his or her health. Paragraph 2 states

19 This Article reaffirms the principle introduced in Article 8 (Right to respect for private and family life) of the *European Convention on Human Rights* and reiterated in the *Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data*. These instruments also give us the term 'private life'. During the drafting of the Convention and its Protocols, several experts commented that 'privacy' would be more appropriate in modern English usage, but the terminology of the aforementioned instruments was retained in order to make clear the links to their enunciated principles and related case law.

that everyone is entitled to know any information collected about his or her health, but also states that the wishes of individuals not to be informed shall be observed.[20] These rights are qualified by the third paragraph, which states that in exceptional cases restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient. It is also noted in the Explanatory Report that the right to know or not to know may be restricted on the basis of Article 26(1) in order to protect the rights of a third party or of society.

Requirements for research to be undertaken on persons in the fields of biology and medicine are set out in the Convention's Chapter on Scientific Research specifically and in other chapters. The Convention and its *Draft Additional Protocol on Biomedical Research* apply to all biomedical research involving interventions on human beings. The general rule for scientific research is set out in Article 15. It states that scientific research in biomedicine shall be carried out freely,[21] subject to the provisions of the Convention and the other legal provisions ensuring the protection of the human being. The fundamental principle for research involving human beings, as in the rest of the Convention, is the free, informed, express, specific, and documented consent of the person(s) taking part.

The Convention also stipulates additionally (in Article 16) that research on a person may only be undertaken if all the following conditions are met:[22]

i. If there is no alternative of comparable effectiveness to research on humans;
ii. the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;
iii. the research has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;
iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;

20 The Explanatory Report notes that the exercise of the right not to know this or that fact concerning his or her health is not regarded as an impediment to the validity of his or her consent to an intervention. The example is given of a person validly consenting to the removal of a cyst despite not wishing to know its nature.

21 The freedom of scientific research is a constitutionally protected right in some of the Member States. See for example, Article 20 of the Swiss Constitution.

22 These conditions were largely inspired by Recommendation No R (90) 3 of the Committee of Ministers to Member States on medical research on the human being.

v. the necessary consent has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Particular attention is being paid in the Council of Europe to the fulfilment of the requirement for multidisciplinary review of the ethical acceptability of biomedical research. First of all, this is being done through a more detailed examination of the subject of ethical review and ethics committees in the additional *Protocol on Biomedical Research.* This will serve to harmonize the principles of ethical review of research involving human beings in Europe. Additionally, the Council has been undertaking a program of cooperation in the years 1997–2002 with its member countries in central and Eastern Europe and elsewhere called the Demo Droit Ethical Review of Biomedical Research Activity (DEBRA). The program consists of multilateral and bilateral meetings, study visits and informative materials on best practice in this field in Europe. This activity previously had been supported by the European Commission and Norway.

The independence of these committees is paramount. As Senator Claude Huriet, who served as a rapporteur for a DEBRA meeting in Vilnius, writes in the French Senate report on the Protection of Persons Undergoing Biomedical Research, the independence of the committees is the foundation of their credibility and legitimacy.[23]

The Convention pays specific attention to the protection of persons not able to consent to research and of embryos in vitro. Article 17 deals with protection of persons not able to consent to research and sets out that research on a person not able to consent to research may only be undertaken if:

– The conditions just mentioned from Article 16, which are applicable to all research, are fulfilled;
– the persons to undergo research have been informed of their rights and the safeguards prescribed by law for their protection;
– the results of the research have the potential to produce real and direct benefit to his or her health;
– research of comparable effectiveness cannot be carried out on individuals capable of giving consent;
– the necessary authorisation provided for under Article 6 (of the Convention) has been given specifically and in writing; and
– the person concerned does not object.

Article 17 also provides exceptionally and under the protective conditions prescribed by law that research which does not have the potential to produce

23 C. Huriet, "La protection des personnes se prêtant à des recherches biomédicales. La rôle des comités: un bilan et des propositions", *Les Rapports du Sénat,* No. 267, 2000–2001, p. 15.

results of direct benefit to the health of a person not able to consent to research may be carried out if stringent conditions are fulfilled. In addition to the aforementioned requirements for research on persons not able to consent, it adds that the research has the aim of contributing, through significant improvement to the scientific understanding of the individual's condition, disease, or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition. Finally, the research must entail only minimal risk and minimal burden for the individual concerned.

A key issue for biomedical researchers in the EU and Council of Europe countries is how to observe ethical review requirements in multi-centre research which may be foreseen in a number of EU and non-EU countries party to the Convention, and in non-party countries, without seriously delaying the start of the research due to a multiplicity and diversity of procedures for obtaining opinions from ethics committees in various regions. At the same time, adequate ethical review of such research must be assured.

Article 18 states that where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo and stipulates that the creation of human embryos for research purposes is prohibited. This does not mean that research on supernumerary embryos created for fertilisation, purposes is prohibited by this Article. As noted above, an additional *Protocol on the Protection of the Human Embryo and Foetus* is under preparation by a working party under the authority of the CDBI.

2.2 *The Draft Additional Protocol on Biomedical Research*

The *Draft Protocol on Biomedical Research* was declassified for consultation by the CDBI in June 2001. It is expected that having received the feedback from this consultation, the Working Party on Biomedical Research will meet in late spring 2002, and will make any necessary modifications to the text. It would then be submitted further to the CDBI and to the Committee of Ministers for adoption. Therefore, in its present form it is a draft, but one that embodies the guidance that the Working Party on Biomedical Research wished to impart. When it comes into force, the provisions of the Protocol's Article 1 to 36 will be regarded as additional articles to the Convention on Human Rights and Biomedicine for the Parties, and all the provisions of that Convention shall apply accordingly.

The Draft Protocol's Preamble stresses that its paramount concern is be the protection of the human being participating in research and affirms that particular protection should be given to human beings who may be vulnerable in

the context of research. It further recognises that every person has a right to accept or refuse to undergo biomedical research and that no one can be forced to undergo it.

Article 1 (object and purpose) states that Parties to the Protocol shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to any research involving interventions on human beings in the field of biomedicine. This is an adaptation of Article 1 of the Convention itself.

The full range of biomedical research activities involving any kind of intervention on human beings are covered by the Draft Protocol. The term 'intervention' must be understood here in a broad sense; in the context of this Protocol it covers all medical acts and interactions relating to the health or well-being of persons in the framework of health care systems or any other setting for scientific research purposes. The Protocol covers all interventions performed for the purposes of research in the fields of preventive care, diagnosis, treatment, or rehabilitation. Here the Protocol is merely following the definition of intervention used by the Convention, applying it here to the specific field of biomedical research. Questionnaires, interviews and observational research taking place in the context of biomedicine constitute interventions if there is contact with the person. In the case of observational research, the existence or lack of contact with the person subject to the research constitutes the dividing line between what is an intervention and what is not. It should be remembered that even questions or interviews could be profoundly troubling to a research subject if they address a sensitive sphere of that person's private life, such as a previous or current illness. One ramification of defining such research as coming within the scope of this Protocol is that review by an ethics committee would be required. The ethics committee could point out any potential problems in the research project to those submitting it for review. The Protocol does not address established medical interventions independent of a research project, even if they result in biological materials or personal data that might later be used in biomedical research. However, research interventions designed to procure biological materials or data are within the scope of this Protocol.

The Draft Protocol does not address research on archived biological materials and data. This is a point on which it differs from the World Medical Association's Declaration of Helsinki (adopted at its 52nd General Assembly in Edinburgh, Scotland, October 2000),[24] which 'includes research on identifiable

24 The Declaration of Helsinki is a set of professional rules for all biomedical researchers adopted by the World Medical Association. The Declaration is aspirational rather than

human material or identifiable data'. Earlier drafts of the Protocol had included these subjects within its scope, but it was decided that they would be better dealt with in a separate report and/or legal instrument after further consideration of the rapidly changing field. Consequently, this draft Protocol will not serve as guidance to Estonian, Latvian and other policymakers in cases where they are dealing with research on archived materials or data, which had been collected for another reason. However, these biological materials and personal data can pose the same types of risks in regard to breach of confidentiality or genetic discrimination as those collected specifically for research purposes, so this second report/instrument will be eagerly awaited when it is completed and made public.

The Draft Protocol does not apply to research on embryos *in vitro*, but does apply to research on embryos *in vivo.* This is despite the fact that there is a separate protocol being developed on the protection of the human embryo and foetus. It was considered that since the Protocol would address research on pregnant women, as a subset of the larger group of persons, it would illogical to try to split that research from the attendant benefits, risks or impact on the embryo *in vivo* or foetus.

It is worthwhile noting that the Draft Protocol, like the Convention, will apply to both privately funded and State funded research. This is in contrast to the approach of the United States, which has often regulated only federally funded research, though there are exceptions (research coming under the authority of the U.S. Federal Drug Administration, for instance).

Further, the Draft Protocol asserts the primacy of the human being, stating that the interests and welfare of the human being participating in research shall prevail over the sole interest of society or science. It is an adaptation of the general rule found in Article 15 of the Convention. Article 4 sets out the general rule of freedom of research, subject to the provisions of this Protocol and of other legal provisions ensuring the protection of the human being. The Protocol states that research is only justified if it has the potential to generate scientific understanding that may be a basis for improvements in human health, and if there is no alternative of comparable effectiveness to utilising human beings in research. Comparable effectiveness refers to the foreseen results of the research, not to individual benefits for a participant. Research on

legally binding, but it has had a great influence especially on members of the medical profession in Estonia, Latvia and Lithuania. It is seen as a valuable 'soft legal' instrument. See P. Zilgalvis, "The European Convention on Human Rights and Biomedicine: Competition for the Declaration of Helsinki?" in *Freedom and Control of Biomedical Research: The Planned Revision of the Declaration of Helsinki* (Springer, 2000), pp. 261–271.

human beings is the last recourse for biomedical researchers. Invasive methods will not be authorised if other less invasive or non-invasive methods can be used with comparable effect. Alternatives to research on human beings could include computer modelling or research on animals. This does not imply that the Draft Protocol authorises or encourages using alternatives that are unethical. The Protocol does not evaluate the ethical acceptability of research on animals, using computer models or other alternatives. These matters are addressed by other legal instruments, such as the Council of Europe Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (1986), and professional standards.

The Draft Protocol states that research shall not involve risks to the human being disproportionate to its potential benefits. When medical research may be of direct benefit to the health of the person undergoing research, a higher degree of risk may be acceptable provided that it is in proportion to the possible benefit. For example, a higher degree of risk may be acceptable on a new treatment for advanced cancer, whereas the same risk would be quite unacceptable where the research is aimed at improving the treatment of a mild infection. A direct benefit to a person's health signifies not only treatment to cure the patient but also treatment that may alleviate suffering thus improving his/her quality of life.

Further, research without potential direct benefit for the participant is addressed. Such research may only be authorised if the research has the aim of contributing, through significant improvement in the scientific understanding of health, disease, or disorder to the ultimate attainment of results capable of conferring benefit to the health of others; and the research entails acceptable risk and acceptable burden for the research participants This category of research includes all non-therapeutic research, including that undertaken on the so-called 'healthy volunteers'. The question of whether or not the risk and burden are acceptable will be considered carefully by the ethics committee and competent body that approve the research project. The final decision on whether or not the risk and burden are acceptable will be made by the person concerned when the person decides whether to consent to participate in the research. Because these participants are capable of consenting to participation in research, the level of risk and burden permitted (acceptable) is higher than that allowed for persons not able to consent (minimal risk and minimal burden).

The Draft Protocol's Article 9 requires that research only be undertaken if the research project has been approved by the competent body in conformity with national law, after independent examination of its scientific merit, and multidisciplinary review of its ethical acceptability by an ethics committee in

conformity with Articles 10 (scientific quality) and 11 (independent examination by an ethics committee). This further develops the aforementioned requirements of review and approval in Article 16 of the Convention. It is acknowledged that in some countries, the ethics committee could also act as the competent body while in other cases or in other countries, the competent body might be a Ministry or a regulatory agency (for pharmaceuticals, for instance), which would take the opinion of the ethics committee into account in formulating its decision. This provision is not intended to curtail the freedom of research. In fact, Article 4 of this Protocol states that biomedical research shall be carried out freely. However, this freedom is not absolute. It is qualified by the legal provisions ensuring the protection of the human being. Independent examination of the ethical acceptability of the research project by an ethics committee, and the approval of that project, is one such protective provision. Allowing unethical research to utilise human beings would contravene their fundamental rights. It is the responsibility of Parties to designate, within the framework of their legal system, the ethics committee or a different competent body that would act as the decision making organ in order to protect those taking part in the research.

In addition, the Article states that consideration must be given to the relevance of the research to the health needs of the local community when reviewing the research project. In most cases, such relevance will be a factor in a positive opinion on the research project by an ethics committee and approval by the competent body (be that the same ethics committee or another body). This does not mean that in all cases where the research is not relevant to local health needs it must not be approved. The example may be given of a phase of research undertaken in an urban European or North American setting where the results will be of relevance to a cure for a tropical disease; especially where the research would involve volunteers capable of giving consent, there should be no strict prohibition on participating in such research out of solidarity. Such research has, in fact, been often undertaken at the National Institutes of Health in the United States. What the provision is seeking to prevent is the 'export' of research in order to avoid stringent ethical standards or in order to find volunteers in another country because they cannot be found in the home country of the researchers.

Chapter III of the Draft Protocol addresses ethics committees and opens with Article 11 on independent examination by an ethics committee. It requires that research projects be submitted to independent examination in each country in which any research activity is to take place. This includes countries from which research subjects are to be recruited for research physically carried out in another country. Best practice is to also submit research projects to an ethics

committee in every research location within countries. All research projects within the scope of this Protocol must be submitted for review, but the Draft Protocol does not address archived biological materials or data. However, this does not exclude the submission of biomedical research based on archived personal data or biological materials from submission to an ethics committee. These fields of research are simply not addressed under the scope.

Due to the differing systems in use in various countries, the Article refers to ethics committees. It was considered that this term covers ethics committees or other bodies authorised to review biomedical research involving interventions on human beings. In many countries this would refer to a multidisciplinary ethics committee but review by a scientific committee might also be required. The Article does not require a positive assessment by the ethics committee being that the role of such bodies or committees in many countries may be solely advisory. The conclusion of this assessment may have legal force in some jurisdictions while in others it serves to advise the competent body (for example, a regulatory authority) that will make a binding decision on whether the research project can commence.

The Article sets out the purpose of the multidisciplinary examination after the precondition of scientific quality has been met. This purpose, in accordance with the aim of the Convention and Protocol to protect the dignity and identity of all human beings, is to protect the dignity, rights, safety and well being of the research participants. If participants are to be included during the reproductive stage of their lives, care should be taken that the duty of the researcher to provide birth control advice, if appropriate, is fulfilled. Further, it is stated that the assessment of the ethical acceptability shall draw on an appropriate range of expertise and experience adequately reflecting professional and lay views. The existence of an independent ethics committee ensures that the interests and concerns of the community are represented, and the participation of laypersons is important in ensuring that the public can have confidence in the system for oversight of biomedical research. Such laypersons will be not be healthcare professionals nor have experience in carrying out biomedical research. The fact that a person is an expert in an unrelated field, such as engineering or accountancy, does not preclude a person from being able to express lay views within the meaning of this Article. Thus this paragraph further details what is meant by the term 'multidisciplinary'. Thought should also be given to gender and cultural balance in the bodies carrying out the assessment. In creating this body, the nature of the projects likely to be presented for review should also be taken into account, and the committee may need to invite experts to assist it in evaluating a project from a specialised sphere of biomedicine.

Additionally, the ethics committee must give clearly stated reasons for its positive or negative conclusions. Whether the reasoning and conclusions are further considered by the competent body in granting or denying approval, or whether they are regarded as the final say on the research project, the basis for conclusion should be clearly comprehensible both to specialists in the field and to laypersons.

The independence of the ethics committee itself and of the individual members of the committee is addressed in Article 12. It states that Parties shall take measures to assure the independence of the ethics committees and that those committees shall not be subject to undue external influences. The members of the ethics committees must declare all circumstances that might lead to a conflict of interest. If such conflicts arise, those involved shall not participate in the review in question.

Article 13 of the Draft Protocol lists the clear, documented information that must be submitted to the ethics committee by the researcher submitting the project for review. In this version of the Draft Protocol that has been declassified for consultation, this Article is rather long and detailed, serving rather like a checklist for the ethics committee reviewing the research project. The detail of this Article has been criticised, but it is precisely in this extended form that it is able to serve as valuable guidance to the ethics committees in Estonia and Latvia that will be reviewing research utilising the genome databases, and will hopefully also be reviewing the collection of the materials/data for these databases.

Comparing the detail of this Article with other international instruments in the field, such as EU Directive 2001/20/EC and the International Conference for Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use Tripartite Guideline for Good Clinical Practice (GCP),[25] we find that these instruments also list the information that must be submitted to the ethics committee. The difference is that they take a different approach in addressing this requirement in a number of separate places. The Directive lists in Article 6 what the committee shall consider in preparing its opinion and then requires in Article 8 that detailed guidance be drawn up on the application format and documentation to be submitted in an application for an ethics committee opinion. The ICH Guideline includes a list of

25 This is a guideline, rather than a formal international treaty or convention, thus it is not legally binding. It constitutes an agreement between the participating pharmaceutical regulatory agencies. Its strength arises from the desire of the regulatory agencies and industry to harmonise the regulation of clinical drug trials. See D. Sprumont, "Legal Protection of Human Research Subjects in Europe" (1999) 6 *European Journal of Health Law,* pp. 25–43.

documentation that must be submitted to the institutional review board/ethics committee,[26] including the trial protocol/amendments and the investigator's brochure (IB). The necessary contents of both of these documents are described in great detail later in Sections 6 and 7 of the Guideline.

It is worthwhile drawing attention to several items of information that must be submitted to the ethics committee. These include the details of all payments and rewards to be made in the context of the research project; and on any foreseen potential further uses, including commercial uses, of the research results, data or biological materials. It is necessary to note that the list does not exclude the ethics committee from requesting additional information necessary for evaluation of the research project.

The Draft Protocol does not prohibit payments to research participants or to the researchers themselves, but in the interests of transparency requires that the ethics committee be informed. With this information, the ethics committee might conclude, for example, that a payment to a research subject is excessive in relation to the inconvenience caused and is, in fact, an inducement to accept a higher level of risk. On the other hand, lucrative financial incentives to a doctor to sign up a large number of patients for a research project might call into question the physician's objectivity in explaining the positive and negative aspects of participation to his patients.

The Protocol also does not take any stand on patenting or on commercial use of research results, data, or biological materials. Rather, it acknowledges the fact that the motivation for participation in biomedical research for many persons may be out of solidarity, and information on foreseen commercial uses of their contribution to the research may be important to them in making a decision on whether to take part or not. Again in the interests of transparency, this Article requires informing the ethics committee reviewing the research project and the potential research participant (in Article 16) of such foreseen uses of the results, data or biological materials.

Article 14 states that the ethics committee must be satisfied that no undue influence, including financial gain, will be exerted on persons to participate in research. Article 15 states that the ethics committee must be satisfied that dependent persons and vulnerable groups will not be subjected to undue influence. If the ethics committee is not satisfied regarding undue influence, then the project should not receive a positive assessment unless changes are made to address the problem. Article 15 sets out the principle that the ethics

26 The term 'institutional review board' or IRB is more frequently used in the United States than 'ethics committee'.

committee must make a special effort to determine that undue influence is not being exerted on dependent persons or vulnerable groups.

Dependent persons may be described as people whose decision on participation in a research project may be influenced by their reliance on those who may be approaching them with the possibility of such participation. Several examples are; persons deprived of their liberty, recipients of health care dependent on their health care provider for continued care, medical or other students, persons in military service, health care workers (particularly those in junior positions) or employees. One could say that all research participants are vulnerable to harm, since research by definition involves uncertainty. At the same time, some human beings may be more vulnerable than others in the context of biomedical research. Persons asked to take part in research could be classified as being vulnerable due to cognitive, situational, institutional, deferential, medical, economic, and social factors.

Chapter IV addresses consent and information. As mentioned above, Article 16 requires that the persons being asked to participate in a research project be given adequate information in a documented and comprehensible form on the purpose, overall plan and methods to be applied in the research project, including the opinion of the ethics committee, according to national law. Further, it lists the items of information that they must receive. The same items of information must be furnished to those asked to provide authorisation for the participation of a person in research (Article 19).

Consent to participation in biomedical research is addressed by Article 17. As noted above, informed consent is a fundamental principle of the Convention, in regard to medical or research interventions. This Article states that no research on a person may be carried out under the provisions of Chapter IV without the informed, free, express, specific and documented consent of the person. Such consent can be freely withdrawn by the person at any phase of the research. Refusal by the person to give consent or the withdrawal of consent to participate in research shall not prejudice a person's right to receive appropriate and timely medical care.

If the capacity of the person to give informed consent is in doubt, arrangements must be in place to verify whether or not the person has such capacity. Such persons may be those who have not been declared incapable of giving consent by a legal body, but whose capacity to give consent may be questionable due to an accident or due to a persistent or worsening condition. The aim of this requirement is not to set out any particular arrangement for verification, but simply to require that such procedures exist. The arrangements would not necessarily be in the framework of the court system, they could be developed and implemented through professional standards in the medical sphere

for instance. The researcher is ultimately responsible for verifying that the participants from whom he obtains consent have the capacity to give the consent. Information on arrangements for such verification in the context of a specific research project should be submitted to the ethics committee reviewing the project.

If the person in question is not able to give consent, then Chapter V (protection of persons not able to consent to research) applies. Article 18 of this Chapter is based on Article 17 of the Convention, which provides protection for those not able to consent to research. The differences are that it expands on the requirement of the authorisation that is necessary for the participation of the person in the research project and it adds a third paragraph with further protections in regard to the uninterrupted provision of appropriate and timely medical care for those for whom authorisation is not given or who object to participation in the research. In regard to authorisation, it is stated that it must be informed (in compliance with Article 19 on the information to be furnished prior to authorisation), and that account must be taken of previously expressed wishes or objections. It is stated that an adult not able to consent shall as far as possible take part in the authorisation procedure, and that the opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.

Both the Convention and the draft Protocol foresee the possibility of authorising research, under the protective conditions prescribed by law, where there is no potential direct benefit to the research subject if additional conditions are fulfilled. One of these is that the research entails no more than minimal risk and minimal burden. One of the critical comments made about the Convention was that 'minimal risk and minimal burden' was not defined. The Draft Protocol now offers such a definition specifying: 'in terms of the nature and scale of the intervention, the research bears a minimal risk if it is to be expected that it would result, at the most, in a very slight and temporary negative impact on the health of the person concerned. It is deemed that it bears a minimal burden if it is to be expected that the symptoms or unpleasantness will be, at the most, temporary and very slight'. It adds that in assessing the burden for an individual, a person enjoying the special confidence of the person concerned shall assess the burden where appropriate. It might be said that this Article is more explanatory than normative, but its political value in the very sensitive area of research on those not able to consent is unquestionable.

Chapter VI addresses special situations, firstly that of research in emergency clinical situations. Specifically, this Article deals with situations wbere it is not possible to obtain consent or the authorisation referred to in Article 18

paragraph 1. iv (otherwise the aforementioned Articles on consent and authorisation would cover the situation). It stipulates if this is the case, and if the research is of a nature such that it can only be undertaken in emergency situations, the law shall determine whether, and under which conditions, this research can take place. The law must include the specific conditions that research of comparable effectiveness cannot be carried out on persons in non-emergency situations, and that the research project may only be undertaken if it has been approved specifically for emergency situations by the competent body. The Article further specifies that persons participating in the emergency research shall be provided with all the relevant information as soon as it becomes possible. Consent or authorisation for continued participation must be obtained as soon as reasonably possible.

Article 22 of this Chapter addresses research on persons deprived of liberty. It starts with the words 'Where such research is allowed by law', because several Council of Europe Member States prohibit this type of research under any circumstances. Technically, this wording it is not necessary since Article 27 of the Convention specifies that none of its provisions shall be interpreted as limiting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in the Convention. The expression 'wider protection', in the case of a conflict between various rights provided for in the Convention, must be interpreted in the light of the aim of the Convention, the protection of the human being.

Further, for such research to be undertaken it must either, have the potential to produce a significant benefit to the health of the potential research participant; or be aimed at benefiting the health of people deprived of their liberty, and only be possible utilising those deprived of their liberty. Examples of the second alternative would be research on the health condition of persons deprived of their liberty, or on how to prevent the spread of AIDS in prison populations. The Article also requires that particular attention be paid that the condition of Article 15 (undue influence on dependent persons) is fulfilled, and that approval has been given by all competent bodies provided for by law. This final requirement relates to the fact that this could also include a body protecting persons deprived of their liberty and/or regulating their contacts, in addition to the competent body for research.

Research during pregnancy or breastfeeding is also addressed by Article 23 of the Draft Protocol. The provision seeks to balance the interests of the woman or embryo or foetus receiving potential benefits from a research project with the need for special protection of the embryo or foetus in the framework of such research. Obviously, any intervention on the pregnant woman will have some sort of impact on the embryo or foetus. The Article states that such

research may only be undertaken if the conditious listed therein are met. Firstly, that the informed consent and/or authorisation required by law has been obtained. Informed consent or authorisation for the person undergoing research is always required under this Protocol and the Convention, and obviously therefore the consent of the mother is always necessary. However, different approaches exist in various countries in regard to the necessity of consulting the father, or not, in regard to this type of research. Therefore, this provision defers to national law by referring to the informed consent or authorisation 'required by law'.

Secondly, the provision sets out two alternatives justifying this type of research. The first is that the research will potentially benefit significantly and directly the health of the woman or that of the embryo, foetus or child. In regard to this alternative, the risk shall not be disproportionate to the potential direct benefits of that research. The second alternative is where the research has the aim of contributing, through significant improvement in scientific understanding, to the ultimate attainment of results capable of conferring benefit to other embryos, foetuses, children or women and where research of comparable effectiveness cannot be carried out on women who are not pregnant or breast feeding. If utilising this alternative, there shall be only minimal risk and minimal burden.

Chapter VIII deals with confidentiality and the right to information. It provides for the confidentiality of any information of a personal nature obtained during biomedical research, the accessibility to research participants of information collected on their health, the availability of research results, and protection of information related to the research.

Safety and supervision are addressed by Chapter IX. Articles are included on; safety of research, re-examination of ongoing research projects if relevant developments or unforeseen events arise during the research, required renewed informed consent or authorisation if appropriate given the events or developments that have arisen, assessment of the health status of potential participants, non-interference of research with necessary clinical interventions, duty of care and ethics follow-up. Article 30 states that placebo treatment may only be used in cases where there is no treatment of proven effectiveness, or where withdrawal or withholding of active treatment does not present unacceptable risk or burden.

Article 33 in this Chapter addresses research in States not party to the Protocol. It sets the requirement that sponsors and researchers based in the territory of a Party to the Protocol who plan research in a State not party to the Protocol, must satisfy both the conditions applicable in the State or States in the territory

of which research is to be carried out and the fundamental ethical standards and safety guarantees laid down in the Protocol. An example of how this Article would work is if the non-Party State does not require independent ethical examination of research projects then the project in question should be reviewed in the State Party to the Protocol. This does not imply that the State Party to the Protocol has the authority to approve research in the non-Party State if that State does not approve the research, or to override its regulations but that researchers from the Party State may be required to observe additional conditions, in accordance with the Protocol, to those applicable in non-Party States if they chose to conduct research there. The wording 'researchers and sponsors based in a State party to this Protocol' signifies those provisions requiring Parties to provide appropriate judicial protection to prevent or put a stop to an unlawful infringement of the rights and principles set forth in the Protocol at short notice, appropriate compensation for research participants in the event of damage according to the conditions and procedures prescribed by law, and appropriate sanctions to be applied in the event of infringement of the provisions contained in the Protocol who have resident status (temporary or permanent) in that State or are citizens of that State, unless they have the status of permanent residents elsewhere.

Chapter X (infringement of the provisions of the Protocol) includes Article 38 which provides for re-examination of the Protocol within the Committee referred to in Article 32 of the *Convention on Human Rights and Biomedicine* no later than five years from its entry into force, and thereafter at such intervals as the Committee may determine. Article 32 of the Convention identifies this Committee as the Steering Committee on Bioethics (CDBI), or any other Committee so designated by the Committee of Ministers.

Article 39 of the Draft Protocol deals with wider protection. In pursuance of this Article, the Parties may apply rules of a more protective nature than those contained in the Protocol. In other words, the text lays down common standards with which States must comply, but at the same time allows them to provide greater protection of the human being and of human rights with regard to biomedical research. A conflict may arise between the various rights established by the Protocol, for example between a scientist's right of freedom of research and the rights of a person submitting to the research. However, the expression 'wider protection' must be interpreted in the light of the purpose of the Protocol, as defined in Article 1, namely the protection of the human being with regard to any research in the field of biomedicine. In the example cited above, any additional statutory protection can only mean greater protection for a person participating in research.

3 Genetic Discrimination

Returning to the body of the *Convention on Human Rights and Biomedicine* itself, its Chapter IV (human genome) is relevant to research and other interventions specifically in the genetic field. This Chapter seeks to prevent the use of genetic tests for purposes that may be selective or discriminatory. The right to be free from discrimination is a fundamental human right, and is part of international human rights instruments like the *Universal Declaration of Human Rights* (Article 2), the *International Covenant on Civil and Political Rights* (Articles 2 and 26), the *International Covenant on Economic, Social and Cultural Rights* (Article 2, paragraph 2), and the *European Convention on Human Rights* (Article 14). The *Convention on Human Rights and Biomedicine* is the first and, until now, only binding international legal instrument that identifies genetic heritage as one of the grounds for non-discrimination.[27]

The *Charter of Fundamental Rights of the European Union* prohibits any discrimination based on genetic features in its Article 21 (non-discrimination). Although this Charter is influential, its legal status is unclear at the moment. It could be described as having a declaratory nature in the present scheme of things in the European Union. However, Mr. Romano Prodi, President of the European Commission stated, 'In the eyes of the European Commission, by proclaiming the Charter of Fundamental Rights, the European Union institutions have committed themselves to respecting the Charter in everything they do and in every policy they promote'.[28] Furthermore, it has been proposed that any future European Union 'Constitution' could integrate the *Charter of Fundamental Rights.*[29] Other commentators have stated that, in any case, it is the most modern international instrument addressing human rights and will be a very influential source for legal argumentation.[30] Therefore, it could be concluded that, in addition to Denmark, which has ratified the *Convention on Human Rights and Biomedicine*, the other European Union Member States and candidate countries around the Baltic Sea also have a duty to prohibit genetic discrimination.

27 A. Hendriks, "Genetics, Data Protection and Non-Discrimination: Some Reflections from an International Human Rights Law Perspective" (2001) 20 *Medicine and Law* 1, pp. 37–49.

28 <https://www.europarl.europa.eu/> accessed on 9 July 2001.

29 *Assemblée Nationale, Délégation pour l'Union Européenne, Compte Rendu No. 149, Réunion du 19 juin 2001, audition de M. Jacgues Delors,* <www.assemblee-nationale.fr/europe> accessed on 9 July 2001.

30 E. Levits, "Cilvēktiesības Eiropas Savienības tiesību sistēmā" (2000) 2 *Likums un Tiesības,* 11(15), p. 335.

Article 11 of the Convention specifically enunciates the principle that any form of discrimination against an individual because of his or her genetic heritage is prohibited. It is interesting to note that the Convention uses the term 'genetic heritage', while the Charter opts for 'genetic features'. Meanwhile, UNESCO's *Universal Declaration on the Human Genome and Human Rights* states in its Article 6 that no one shall be subjected to discrimination based on genetic 'characteristics'.

This prohibition in Article 11 of the Convention expands the protections of Article 14 of the *European Convention on Human Rights,* which states that the enjoyment of the rights and freedoms set forth in the Convention must be secured without discrimination on the basis of sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status, to include genetic heritage.

The Explanatory report notes that this prohibition of discrimination applies to all areas included in the field of application of the *Convention on Human Rights and Biomedicine.* This notion also includes non-discrimination on grounds of race as understood by the 1965 United Nations *Convention on the Elimination of all Forms of Racial Discrimination* as interpreted by the Convention Committee (CERD). Discrimination must be understood as unfair discrimination. The Explanatory Report states that this prohibition cannot prohibit positive measures implemented with the goal of re-establishing a certain balance in favour of those at a disadvantage because of their genetic inheritance.

An example of the positive influence of the Convention and/or the Charter can be found in the *Draft Latvian Law on Human Genome Research* sent to the Committees of the Parliament in June 2001, which prohibits discriminating against a person on the basis of a person's DNA structure or on the basis of the person being or not being a gene donor. Again, the basis for discrimination differs slightly here; it is the 'DNA structure' in this instrument. Additionally, a further ground for non-discrimination is added, that of being a donor or not being a donor. It could be said that this requirement is analogous to the requirement of the *Convention on Human Rights and Biomedicine* and its Protocol that a potential research participant has the right to withdraw or refuse consent (and should not suffer for choosing to exercise this right).

3.1 *The Convention and Genetic Therapy*

Article 12 states that tests which are predictive of genetic diseases or which serve to identify the person being tested as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to

health purposes, and subject to additional genetic counselling. Thus research utilising such tests should be undertaken in the context of developing medical treatment and enhancing the possibility to prevent disease.

Article 13 states that interventions seeking to modify the human genome may only be undertaken for preventive, diagnostic, or therapeutic purposes and only if the aim is not to introduce any modification in the genome of any descendants. The Explanatory Report explains that medical research intending to genetically modify spermatozoa or ova that are not for procreation is only possible *in vitro* with appropriate ethical or regulatory approval. Provisions regarding genetic research are currently being developed further, primarily in the additional *Protocol on Human Genetics,* but also, in a more general sense, including ethical review of research, in the additional *Protocol on Biomedical Research.* The Working Party preparing the additional *Protocol on Human Genetics* is also considering issues such as; access to genetic services, individual genetic testing, genetic screening programmes, non-stigmatisation, interventions on the human genome, genetic counselling, applications of genetics related to employment, applications of genetics related to insurance, applications of genetics related to identification, and the protection of private life.

Article 21 prohibits financial gain from the human body and its parts.[31] The issue of financial gain arising from the human body or its parts will be addressed further in the context of biomedical research in the additional *Protocol on Biomedical Research* and in a related report addressing research on biological materials.

While there is no possibility for recourse to the European Court of Human Rights at this time in regard to individual cases connected to the Convention, Article 29 of the Convention provides that the European Court of Human Rights may give advisory opinions concerning interpretation of the Convention at the request of the Government of a Party or the CDBI (with membership restricted to the Parties to the Convention for this question). Additionally, it requires any Party to furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention if so requested by the Secretary General of the Council of Europe.

As we are dealing with such a rapidly changing field, Article 32 provides that the Convention shall be re-examined no later than five years from its entry into

31 The Explanatory report notes that the question of patents was not considered in connection with this provision; accordingly it was not intended to apply to the issue of the patentability of biotechnological inventions.

force (1 December 1999) and afterwards at intervals determined by the Committee in charge of its re-examination.

4 Cloning

The additional *Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings* opened for signature on 12 January 1998 and came into force on 1 March 2001. The Protocol has been signed by 29 Council of Europe Member States[32] and has been ratified by eight.[33] The Protocol follows from the principle of protecting human dignity found in Article 1 of the Convention; also from Article 13, which provides that an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic, or therapeutic purposes, and only if its aim is not to introduce any modification in the genome of any descendants; and from Article 18 which ensures the protection of the embryo *in vitro* in the framework of research and forbids the creation of embryos specifically for use in research.

Article 1 of the Protocol states that any intervention seeking to create a human being identical to another human being, whether living or dead, is prohibited. The next paragraph explains that for the purpose of this article, the term human being 'genetically identical' to another human being means a human being sharing with another the same nuclear gene set.

In conformity with the approach followed for the *Convention on Human Rights and Biomedicine,* the Protocol leaves it to domestic law to set the scope of the expression 'human being' in regard to the application of the Protocol. The Explanatory Report to the Protocol explains that the term 'nuclear' means only that genes of the nucleus, not the mitochondrial genes, are examined in regard to identity, which is why the prohibition of human cloning also extends to all nuclear transfer methods which seek to create identical human beings. The term used in the additional Protocol, 'the same nuclear gene set', takes into account the fact that some genes may undergo somatic mutation during development. As it is known, monozygotic twins who have developed from a single fertilised egg will share the same nuclear gene set, but may not have genes that are 100 per cent identical. The Protocol does not intend to discriminate in any

32 As of I October 2001: Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Moldova, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, The Former Yugoslav Republic of Macedonia, and Turkey.

33 As of 1 October 2001: Czech Republic, Georgia, Greece, Portugal, Romania, Slovakia, Slovenia, and Spain.

way against monozygotic twins occurring naturally. It also does not intend to address hormone stimulation to treat infertility in women, which may result in twins being born.

In regard to biomedical research, cloning cells and tissues is an ethically acceptable and valuable biomedical technique, particularly important for the development of new therapies, and is not addressed by the prohibition in the Protocol. It does not intend to prohibit cloning techniques utilised in cell biology.

There are different points of view, however, regarding the ethical acceptability of cloning undifferentiated cells of embryonic origin. Article 18 of the Convention ensures adequate protection of the embryo *in vitro* in those States in which such research is allowed and it is suspected that this subject will be looked at in the additional Protocol on the Protection of the Human Embryo and Foetus. Thus, it is necessary to distinguish between cloning of cells as a technique, use of embryonic cells in cloning techniques, and human cloning utilising processes such as embryo splitting or nuclear transfer. The first activity is ethically acceptable, the second is under examination, and the third falls under the prohibition foreseen by the Protocol. It is important to note that none of the instruments define what an 'embryo' is.

The ethical rationale behind the prohibition of the third activity, the cloning of human beings, is firstly that deliberately cloning human beings would present a threat to human identity because it would mean giving up the indispensable protection against predetermination of the human genetic constitution by a third party. Secondly, it is reasoned that human dignity would be endangered by instrumentalisation of human beings through artificial human cloning. Thirdly, since it is thought that naturally occurring genetic recombination is likely to create more freedom for the individual than a predetermined genetic make-up, it follows that it is in the interest of defending human rights and dignity to keep the essentially random nature of the composition of an individual's genes.

5 Conclusions

The potential benefits created by technology, science and medicine are vast, but without the adequate supervision that a functioning ethical and legal framework offers, this potential for improvements in health and living standards could be misused to other ends. In conclusion, by protecting human rights and dignity in the context of the new biomedical technologies, the Convention helps to provide assurance that the positive implications of such

activities will be appreciated and supported while threatening developments which alarm the people of the Baltic region, other parts of Europe and the rest of the world are not allowed to blacken the image of biomedicine and biomedical research. The positive appreciation of progress in biology and medicine can only be increased by the guarantee that there is an ethical and legal basis for evaluating such undertakings.

Other activities of the CDBI also look to the future, though they are not expected to result in legally binding instruments in the near future. Examples are the Working Parties on Xenotrausplantation, Biotechnology and Psychiatry and Human Rights. A different perspective is provided by the Standing Conference of European National Ethics Committees (COMETH), which receives secretarial support from the Council of Europe Secretariat. COMETH provides an opportunity for the national ethics committees to come together bi-annually to discuss practical and ethical aspects of their work, as well as to extend assistance to Council of Europe Member States wishing to create national ethics bodies. National ethics committees were established during the 1990's in Estonia, Latvia, and Lithuania. The Committees have taken an active part in the work of COMETH. Conferences and symposia, such as the 1999 International Conference of the Council of Europe that focused on ethical issues arising from the application of biotechnology, will continue to be organised.

Finally, it is recognised that there is a need for international cooperation in this field to extend the same protections for the individual in this field foreseen in the Convention on Human Rights and Biomedicine beyond Member States of the Council of Europe, and beyond the Baltic Sea region. A debate on bioethical issues is ongoing in international organisations such as the World Health Organisation, UNESCO, and OECD, among others. A number of observers have noted the tendency toward a certain homogenisation, in a positive sense, of the law in the field of bioethics in the Baltic region and in Western Europe, in general. However, differences do remain between the approaches followed in the United Kingdom and the Continent, and even more so between Europe and some of the Asian countries. Therefore, it might be presumptuous to offer the solutions agreed upon in Europe for the Convention as a template for a future international agreement, but the experience of the Convention, being the first legally binding instrument addressing the new biomedical technologies and already having had tangible influence on national legislation adopted in its wake, could certainly be useful for a future, geographically expanded discussion.