

**Comparing guidelines on biobanks:  
emerging consensus and unresolved controversies**

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## **ABSTRACT**

*In this paper, we present a comparative analysis (conducted in 2004-2005) of twenty seven policies on biobanks. The paper is structured around the three separate stages of the biobanking process (collection, storage and use of both human biological samples and data) and for each stage, we then focus on salient issues that have been debated by scholars and have been addressed by the drafters of the policies we compare. Although consensus exists on few issues and solutions, our conclusion is that existing policies do not address in sufficient detail, or do not agree on, a number of important issues raised by biobanking activities. Therefore, much empirical and theoretical work has to be done on this topic in order to highlight possible areas of disagreement on the different principles and policy arrangements and to clarify the terminology that the guidelines adopt.*

## EXECUTIVE SUMMARY

**The question.** Biobanking activities raise highly complex ethical issues in health policy, especially whenever biological samples are stored and used in combination with information on individuals' health, lifestyle or genealogy. Several countries have addressed the problems presented by biobanks. Iceland, Estonia, and Sweden have enacted laws. National bioethics advisory committees have issued reports and recommendations specifically addressing biobanking activities. International organizations have also started to tackle the issue and have prepared declarations and other normative texts. In this paper, we present a comparative analysis of the policies on human biological sample collections and on genetic data to critically assess whether the existing guidelines provide a satisfactory policy framework to regulate biobanks.

**Methods.** We compared twenty-seven policies on biobanks structured around the three separate stages of the biobanking process (collection, storage and use of both human biological samples and data) (see Appendix 1). For each stage, we have focused on salient issues that have been debated by scholars and have been addressed by the drafters of the policies we compare.

**Results.** The comparative analysis of the policies that we have included in the study shows the contradictory or inconclusive nature of the existing guidelines. However, the analysis also shows that there is some policy consensus, albeit on a limited number of issues. Most policies require that a written, informed consent must be collected, at least once in the process, for samples and data to be collected and stored in a genetic database. It is also widely acknowledged that using already collected samples and data is acceptable if it is impossible to re-new the already taken informed consent, or obtain a new informed consent, from the sample source. Most of the guidelines also provide that the financial incentives offered to research participants must never be excessive, i.e. constituting undue influence to participate in genetic research. However, the determination of whether information that is provided to research participants at the time of the sample collection is adequate and whether using samples and/or data for further research that had not been specified at the time of consent is permissible remains a matter of controversy. Whether consent of the individual needs to be complemented by consent of others concerned, such as the family or community is also undetermined. Moreover, it is controversial whether samples taken during clinical or research activities should require informed consent in order to allow inclusion in genetic databases and whether irreversibly anonymized tissue can be used in genetic research without informed consent.

The majority of guidelines also recognize research participants' right to withdraw their consent. However, several issues remain controversial (what is the best mechanism to implement the exercise of participants' right of withdrawal) or inconclusive (whether it affects both samples and data and the timing of the exercise of the right of withdrawal, especially in relation to ongoing studies).

Regarding the conditions of storage and use of samples, some form of anonymization of data and samples is commonly required to protect the privacy of the research participants and the confidentiality of the information. Complete anonymization of the samples at the time of the samples collection is rarely recommended. Several issues remain unresolved, namely what must be protected as confidential, what is the best arrangement to ensure that confidentiality is maintained, and who should decide on that. Moreover, policies often use different, and at times unclear, definitions of the various mechanisms of anonymization of data and samples, which adds a layer of further complexity.

Another major area of controversy deals with the rules of ownership and commercialization. Regarding commercialization, it is unresolved whether ownership of samples ought to be assigned to the biobank or to research participants, or even more radically, whether ownership of samples shall be prohibited *tout court*. On the other hand, the policies agree on the fact that the entity responsible for the collection must ensure that the integrity of the sample is protected and that it is used in an appropriate manner. Furthermore, policies are inconsistent on whether or not publicly-funded biobanks may share samples and data with commercial companies. The role of the legal protection of intellectual property (IP) is also controversial. At one extreme a patenting regime that grants patents on gene sequences seems inconsistent with the view that genetic resources are “the heritage of humanity”. On the other hand, many policies recognize IP protection as needed to make commercialization of human genetic research viable, and construe IP rights as the best mechanism for participant to claim “an entitlement to share in any benefits arising from the exploitation of the tissue removed”.

Policies are also conflicting and inconclusive positions on benefit sharing, and in particular disagreement on what kinds of benefits should be shared, with whom those benefits should be shared, and the mechanisms of negotiation of the benefit sharing agreement.

Finally, policies express more agreement on the issue of feedback to participants. Often, research participants are granted a right to know and /or a right not to know. It is controversial, however, whether genetic counseling shall be provided along with feedback, what kinds of information shall be communicated to research participants, whether investigators or biobankers are responsible for communicating the results directly to the research participants rather than to their treating physicians, and whether relatives have a right to know (and not to know) research results.

**Conclusions.** Biobanking activities raise highly complex ethical issues in health policy, especially whenever biological samples are stored and used in combination with information on individuals’ health, lifestyle or genealogy. The comparative analysis of biobank policies shows the contradictory or inconclusive nature of the existing guidelines, policy consensus being reached only on a limited number of issues. Further discussions in the literature and other forums, as well as empirical research, is therefore required.

## I. Identifying challenges to policy efforts on a global scale

The technical possibilities for automated analysis of large DNA sample collections and the bioinformatic processing of the resulting data have developed dramatically during the past several years and are constantly being improved. Protecting the data available in such databases has consequently emerged as a highly complex ethical issue in health policy. The ethical and legal issues become even thornier when genetic data are combined with information on individuals' health, lifestyle or genealogy. In its summary of the most pressing issues raised by advances in genetic research, the 2002 Report of the Advisory Committee on Health Research of the World Health Organization ("WHO") on Genomics and World Health states that "[t]he planned development of large-scale genetic . . . databases offers a series of hazards and ethical issues which have not been encountered before."<sup>1</sup> Among the hazards, the Report raises the issue of the "many ambiguities regarding access and control . . . the potential harm to individuals, groups and communities . . . risks . . . arising from access to genetic information, both by individuals themselves and by third parties."<sup>2</sup> Furthermore, among the challenges that biobanks raise, the Report lists access by "health insurance companies, government bodies, or the legal profession and police" as well as the "the effect of stigmatizing entire countries or particular groups of individuals, and there are concerns about commercial exploitation without adequate compensation."<sup>3</sup>

Several countries have addressed the problems presented by biobanks. Iceland, Estonia, and Sweden have enacted laws. The national bioethics advisory committees of Canada, Brazil, France and Denmark (just to name a few), have issued reports and recommendations specifically addressing biobanking activities. International organizations have also started to tackle the issue and have prepared declarations and other normative texts. In this paper, we present a comparative analysis of the policies on human biological sample collections and on genetic data to critically assess whether the existing guidelines provide a satisfactory policy framework to regulate biobanks (Part II). Although other published studies compare human research genetic databases policies,<sup>4</sup>

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<sup>1</sup> WORLD HEALTH ORGANIZATION. ADVISORY COMM. ON HEALTH RESEARCH, GENOMICS AND WORLD HEALTH 113 (2002).

<sup>2</sup> *Id.* at 114.

<sup>3</sup> *Id.*

<sup>4</sup> Jane Kaye et al., *Population genetic databases: a comparative analysis of the law in Iceland, Sweden, Estonia and the UK*, 8 TRAMES. J. OF THE HUMANITIES AND SOCIAL SCIENCES, 15-33; Anne Cambon-Thomsen, *The social and ethical issues of post-genomic human biobanks*, 11 NATURE REVIEW GENETICS 866-73 (2004); Keith Bauer et al., *Ethical issues in tissue banking for research: a brief review of existing organizational policies*, 25 THEORETICAL MED. 113-142 (2004); Melissa A. Austin et al., *Genebanks: a comparison of eight proposed international genetic databases*, 6 COMMUNITY GENETICS 37-45 (2003); Béatrice Godard et al., *Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues*,

our analysis goes beyond them, and thus enriches the debate, by comparing a wider number of policies and by providing an in-depth analysis, often quoting the language used by the policies, of a wide range of issues arising out of collecting, storing, and using human tissues along with medical and other personal data. Our conclusion is that existing policies do not address in sufficient detail, or do not agree on, a number of important issues (Part III). Therefore, much empirical and theoretical work has to be done on this topic in order to highlight possible areas of disagreement on the different principles and policy arrangements, to point out issues and solutions on which consensus exists, and to clarify the terminology that the guidelines adopt.

In terms of methodology, this paper is based on the analysis of twenty-seven policies – international and regional policy instruments, national laws, opinions issued by national ethics committee and by various national and international organizations – that specifically address biobanks or that discuss aspects of biobanking when dealing with human tissue. The study also draws from policies on biomedical research involving human beings and on the literature on genetic databases and on genetic research with human beings, in particular the published studies comparing biobanking policies. The policies compared in this paper are listed in Appendix 1.

The paper is structured around the three separate stages of the biobanking process: collection, storage and use of both human biological samples and data. We treat these three stages separately both for reasons of clarity in presenting and analyzing the issues and because several issues are specific to the stage one considers. For instance, feeding research finding back to the participants arises only after genetic analysis of the samples is performed and the resulting data are analyzed. Similarly, the issue of offering financial incentives to participants, which arises at the time samples are collected, must be logically distinguished from sharing the benefits of research, which must then be analyzed whenever samples and data are used. For each stage, we then focus on salient issues that have been debated by scholars and have been addressed by the drafters of the policies we compare.

## **II. Comparing guidelines on biobanks**

### **A. Collection**

#### ***1. Informed consent***

The respect of the participants' autonomous choice lies at the heart of the ethics of research that includes human subjects. International documents, national laws and other policies mandate that human subjects cannot be enrolled in research without their free and informed consent. Therefore, all policies discuss informed consent to some extent. Although the policies agree that some form of consent is necessary, the exact form that

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*ownership, return of benefits. A professional perspective*, 11 EUR. J. HUM. GENETICS S88-S122 (Supp. 2 2003); Robert R. Sharp & Morris W. Foster, *An analysis of research guidelines on the collection and use of human biological materials from American Indian and Alaskan Native communities*, 42 JURIMETRICS 165-186 (2002).

this should take is open to debate. Many issues that relate to informed consent are not fully addressed in these policies. Controversial issues include how much information a donor should receive, how to collect consent in a way that is respectful of local cultures,<sup>5</sup> how to collect the consent of minors, and whether community or group consent is required in some circumstances. Given the scope of this paper, we will focus on issues involving consent that are specific to human genetic databases. Moreover, in this section we will concentrate on those issues of informed consent that arise in connection with the collection of samples and data. The issues that arise in connection to the use of samples and data will be addressed at a later stage.

a) *Individual participants*

Often, future uses of samples and data cannot be foreseen at the time when consent is obtained.<sup>6</sup> Genetic databases are often presented as key biomedical resources that enable researchers to a diverse range of research projects, and thus are often not hypothesis-driven. In practice, although participants are informed that, once stored, their samples will be used in biomedical research, “there will be research-related risks that cannot be described to individual participants at the time they are recruited to contribute a sample.”<sup>7</sup> Consequently, biobanking activities challenge the traditional requirement to fully inform participants in genetic research of all uses even if such future uses cannot be foreseen.<sup>8</sup> Policies adopt different views of what consent shall be taken at the time the samples are collected: a broad consent that allows for the use of samples for genetic research in general, a consent describing one specific purpose and extending to all kinds of researches that relate to that purpose, new consent or re-consent from donors before starting any future research project, assumed consent, or exceptionally waiving the informed consent requirement.<sup>9</sup>

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<sup>5</sup> Declaración de Manzanillo de 1996, revisada en Buenos Aires en 1998 y en Santiago en 2001. Declaración Ibero-Latinoamericana Sobre Ética Y Genética, *available at* <http://www.bioetica.bioetica.org/manzanillo.htm>; Samantha Orr et al., *The establishment of a network of European human research tissue banks*, 29 ALTERNATIVES TO LABORATORY ANIMALS 125-134 (2001)(these are in-progress guidelines drafted by the European Network of Research Tissue Banks).

<sup>6</sup> Godard et al., *supra* note 4, at S93.

<sup>7</sup> Sharp & Foster, *supra* note 4, at 171.

<sup>8</sup> NATIONALER ETHIKRAT [GERMAN NATIONAL ETHICS COUNCIL], BIOBANKS FOR RESEARCH 28 (Berlin: Nationaler Ethikrat, 2004) [hereinafter GNEC].

<sup>9</sup> *See also*, Bernice Elger & Alexandre Mauron, *A Presumed-Consent Model for Regulating Informed Consent of Genetic Research Involving DNA Banking*, in POPULATIONS AND GENETICS: LEGAL AND SOCIO-ETHICAL PERSPECTIVES 269-96 (Bartha Maria Knoppers ed., 2003). The issue of using samples and data for purposes other than those explicitly known and disclosed at the time the samples were taken is discussed later in the paper. *See infra*, II.C.2.

First, several guidelines have adopted the view that a *broad consent* that allows for the use of samples for genetic research in general, including future, as yet unspecified research projects, appears to be the most efficient path to follow.<sup>10</sup> In comparing the legal frameworks of Sweden, Iceland, Estonia and the United Kingdom, Kaye et al. found that “[i]n legislation that has been especially drafted for genetic databases it has been seen sufficient that a broad description of the purpose is allowed.”<sup>11</sup> Practical reasons are often cited to support this view. The German Ethics Council’s opinion on biobanks take a similar approach by providing that, “[t]o ensure that biobanks, once established, do not quickly lose their value, it must be made possible for donors to consent to the use of their samples and data for undefined research projects to be specified only at some future date.”<sup>12</sup> Broad consent, and its permissibility, is often recommended only if mechanisms to de-identify samples and data by anonymization are in place.<sup>13</sup>

A second view supports a consent describing one specific purpose and extending to all kinds of researches that relate to that purpose. As a consequence, participants should be given “a clear explanation of the potential scope of the research that may be carried out on their sample or data” at the outset, and a re-consenting is recommended only for research that is of a “*fundamentally different nature*.”<sup>14</sup>

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<sup>10</sup> WORLD HEALTH ORGANIZATION, PROPOSED INTERNATIONAL GUIDELINES ON ETHICAL ISSUES IN MEDICAL GENETICS AND GENETIC SERVICES 13 (Geneva: World Health Organization, 1997) [hereinafter WHO 1997].

<sup>11</sup> Kaye et al., *supra* note 4, at 22. In Iceland, the board of the biobank may authorize uses for purposes other than those for which the samples were originally collected, “provided that important interests are at stake, and that the potential benefit outweighs any potential inconvenience to the donor of a biological sample or other parties.” *See*, Act on Biobanks, no. 100, 2000, art. 9 [hereinafter Ice. Act on Biobanks].

<sup>12</sup> GNEC, *supra* note 8, at 51.

<sup>13</sup> GENETIC DATABASES. ASSESSING THE BENEFITS AND THE IMPACT ON HUMAN & PATIENT RIGHTS. REPORT FOR CONSULTATION TO THE WHO, Recommendation 9 (European Partnership on Patients Rights and Citizens Empowerment - A network of the WHO Office for Europe, 2003)(recommending broad consent only if the “anonymity of future data can be guaranteed”)[hereinafter WHO 2003]. *See also*, U.K. HUM. GENETICS COMM’N, INSIDE INFORMATION BALANCING INTERESTS IN THE USE OF PERSONAL GENETIC DATA 94-95 (2002) (recommending a generalized consent in cases where “irreversible or reversible anonymisation of data and samples” is assured) [hereinafter HGC]. In Australia, “some human genetic databases . . . operate by obtaining consent to unspecified future research.” *See*, AUSTRALIAN LAW REFORM COMMISSION AND AUSTRALIAN HEALTH ETHICS COMMITTEE, ESSENTIALLY YOURS: THE PROTECTION OF HUMAN GENETIC INFORMATION IN AUSTRALIA 481 (Commonwealth of Australia, Canberra, Australia, March 14, 2003).

<sup>14</sup> NARC, *supra* note 38, at chapter 7; POPULATION-BASED LARGE-SCALE COLLECTIONS OF DNA SAMPLES AND DATABASES OF GENETIC INFORMATION 72.c (The Isr. Academy

Opposing to the idea of broad consent, a third group of policies recommend a *specific consent*. As a consequence, these policies exclude at the time of collection that samples and data can be used for any future research project, which had not been determined at the moment of the original consent.<sup>15</sup> Some countries have even provided that broad consent is against the law. For instance, in Sweden, “[t]issue samples stored in a biobank must not be used for other purposes than the ones previously informed about and consented to.”<sup>16</sup> In general, these policies recommend having an informed consent form that describes all known, future uses and re-contacting participants before each, unspecified research project is started.<sup>17</sup> In alternative, other guidelines recommend that participants shall be allowed to waive the right to be re-contacted should the samples be used in new projects.<sup>18</sup>

*Assumed consent* is the option adopted in Iceland. It is defined as:

Consent that consists in the donor of a biological sample not expressing any unwillingness for a biological sample taken from him/her for a clinical test to be permanently preserved in a biobank for use by the terms [specified in the Act], information in writing on this possibility having been available to him/her.<sup>19</sup>

Finally, other policies provide that, under certain circumstances (for instance, in occasion of clinical or diagnostic tests), the individual informed consent requirement *does not apply*. In Kenya, if either impracticable or inadvisable, the relevant ethics review committee may decide that “it is ethically acceptable to proceed without informed

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Comm. for Bioethics, 2002), *available at* <http://www.academy.ac.il/bioethics/english/report2/Report2-e.html>: at 72.c [hereinafter Isr. 2002] (allowing future uses “restricted to similar type of research on genetic diseases (including psychiatric diseases)”). Japanese Guidelines, *supra* note 85, at rule 11, subrules 2-3; HGC, *supra* note 13.

<sup>15</sup> CEST, *supra* note 38, at 48.

<sup>16</sup> Biobanks (Health Care) Act, May 23, 2002, chapter 4, section 5 (Swed.) [hereinafter Swed. Biobanks Act] *See also*, ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH ON HUMAN SUBJECTS 46 (Indian Council of Med. Research, 2000)[hereinafter Indian MRC](the use of the samples shall be limited to the “use for original intent for which consent and approval of Local [Ethics Committee] has been obtained”).

<sup>17</sup> NETWORK OF APPLIED GENETIC MEDICINE, STATEMENT OF PRINCIPLES: HUMAN GENOME RESEARCH 8 (2000)[hereinafter RMGA].

<sup>18</sup> American Society of Human Genetics, *Statement on informed consent for genetic research*, 59 AM. J. HUM. GENETICS 471-4 (1996) [hereinafter ASHG 1996]; RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE (National Bioethics Advisory Commission: Rockville, Maryland, 2000) [hereinafter NBAC].

<sup>19</sup> Ice. Act on Biobanks, *supra* note 11, at art. 3.

consent [for instance in studies involving] anonymous ‘left-over’ samples of blood, urine, saliva tissue specimens.”<sup>20</sup>

To summarize, with few exception, some form of written informed consent is commonly required at least once to permit the individual to consent to the fact that his or her samples are collected and included in a genetic database. However, the policies adopt different views on how “specific” such consent should be, ranging from recommending a broad consent to a consent specifying all future uses.<sup>21</sup>

b) Informed consent and groups

The decision to collect and use samples in biomedical research might affect several individuals. Also, the results obtained from studies involving genetic databases might have an impact not only on the participants, but also on the families, communities, and populations to which they belong. Thus, the storage of human samples may have implication beyond individual participants.<sup>22</sup> On the other, traditionally certain groups and communities take collective decisions on issues that affect the whole group, and some of them have chosen to have a formal structure, with leaders, who have the authority on behalf of the whole group. Finally, an ethical obligation to have group permission or at least consultations may be triggered by the vulnerability of the populations involved in genetic research.<sup>23</sup> Consequently, a number of guidelines recommend not only obtaining the consent of the participants, but also the consent or at least the consultation of all those who share the potential risks and benefits.

Whether the consent of an individual needs to be supplemented by the consent of others concerned is itself a controversial matter. While a number of policies are silent, and few reject the idea of an informed consent that is not exclusively individual,<sup>24</sup> others recommend some form of group involvement, ranging from a generic form of collective involvement to group consent. *Collective involvement* before sample collection may substantiate in explaining the sampling process and the research project thoroughly to the

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<sup>20</sup> National Council for Science and Technology, *supra* note 34, at 14 (recommending that for epidemiological studies community consent must be collected if those studies involve “an entire community rather than [an] individual human subject”).

<sup>21</sup> The issue is further analyzed when discussing uses that go beyond those for which consent was originally given. *See infra*, II.C.2.

<sup>22</sup> Brazilian National Health Comm., *Resolution 340/04: Guidelines for Ethical Analysis of Genetics Research Involving Human Beings*, A.III.1 (8 July 2004) at <http://conselho.saude.gov.br/docs/Reso%20340.doc> [hereinafter Brazil NHC 2004]; National Council for Science and Technology, *supra* note 34, at 14.

<sup>23</sup> Declaración de Manzanillo, *supra* note 5, at fifth.

<sup>24</sup> GNEC, *supra* note 8, at recommendation 24 (providing that, because the “particular problems presented by research on indigenous populations do not arise in Germany,” no group consent is required “in addition to consent of individual donors”).

population and its members who agree to participate, or, more generally, in “involv[ing the] society at large in the decision-making process concerning broad policies for the collection, processing, use and storage of human genetic data.”<sup>25</sup> *Group or public consultation* is one option.<sup>26</sup> The Canadian Science and Technology Ethics Committee (“CEST”) recommends conducting a five-stage “public consultation process” that comprises running a population survey, consulting with the population, consulting with interest groups, drafting a report, and elaborating policies that are consistent with the consultation process.<sup>27</sup> Groups may also be asked to provide a *community or family consent*.<sup>28</sup> However, policies also recommend that, even if group consent is taken, the

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<sup>25</sup> United Nations Educational, Scientific and Cultural Organization, The International Declaration on Human Genetic Data, art.8 (adopted by the General Conference at its 32nd Session on 16 October 2003), *available at* [http://portal.unesco.org/shs/en/file\\_download.php/6016a4bea4c293a23e913de638045ea9Declaration\\_en.pdf](http://portal.unesco.org/shs/en/file_download.php/6016a4bea4c293a23e913de638045ea9Declaration_en.pdf) [hereinafter UNESCO 2003]; *see also*, PROPOSAL FOR AN INSTRUMENT ON THE USE OF ARCHIVED HUMAN MATERIALS IN BIOMEDICAL RESEARCH Art.13 (Council of Europe Steering Comm. on bioethics, 2002) (no “undue influence” shall be exerted)[hereinafter Council of Europe 2002]; Indian MRC, *supra* note 16, 42 (discussing pedigree studies); GUIDELINES FOR ETHICAL CONDUCT OF BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS IN KENYA 11 (National Council for Science and Technology, Kenya 2005).

<sup>26</sup> Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002), *available at* [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm) (hereinafter CIOMS), at commentary on Guideline 8 (recommending that, when epidemiological, genetic or sociologic studies involve risks to groups, “often it will be advisable to have individual consent supplemented by community consultation”); TRI-COUNCIL POLICY STATEMENT: ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS, art. 8.1 (Interagency Secretariat on Research Ethics, Canada, 2005)[hereinafter Tri-Council] (“genetic research involves the family and/or the community, [and thus] free and informed consent shall also involve those social structures, as far as is practical and possible”); RMGA, *supra* note 17 (recommending “prior and ongoing public consultation” whenever population genetic research is undertaken.)

<sup>27</sup> CEST, *supra* note 38, at recommendation 15.

<sup>28</sup> The Human Genome Organization, Ethics Comm’n, Statement on the Principled Conduct of Genetics Research (Statement approved on March 21, 1996, subsequently published in 12 LAW HUM. GENOME REV. 253-55 (2000) [hereinafter HUGO 1996] (endorsing the view that “consent to participate can be individual, familial, or at the level of communities and populations”); NARC, *supra* note 38 (recommending that populations are involved in the project through a multi-stage process, comprising of “determine[ing] whether [the population] is interested in participating in the Project [and the] discussi[ng] with the population, through its members or through culturally and legally appropriate leadership groups”; National Council for Science and Technology, *supra* note 34, at 14 (recommending that for epidemiological studies “the investigators should secure the agreement and cooperation if provincial

consent of the individuals involved is also collected group.<sup>29</sup> Finally, *parliamentary and democratic discussion* is another process by which groups take part in the process of collecting samples, as shown by the enactment of legislation on biobanks in Estonia, Iceland, Sweden and Norway. No guideline expressly states that a parliamentary debate is required before undertaking population-based genetic research. However, critics of the Icelandic biobank point out that the legislative history of the parliamentary discussions in Iceland seem to suggest that “the passage of the . . . Act was rushed and that the legislative process was marked by a surprising lack of community consultation and public debate.”<sup>30</sup>

On other hand, sociocultural arrangements in certain communities may be such that it is an accepted practice that consent to participate in research is given by the head of the family or the tribe. The guidelines in Kenya acknowledge the practice under which “women, particularly married ones, may not give their consent to participant in research without the express permission of their husbands.”<sup>31</sup> The guidelines recommend that “researchers must always follow the principles of getting informed consent”,<sup>32</sup> that is that if a woman “decides not to participate in the research, her decision not to do so must be respected.”<sup>33</sup>

The issue of a collective consent or permission is a controversial one. In fact, when collective permission is recommended, it is unclear, as to which characteristics of the population in question would require prior collective involvement. One such characteristic could be that the members of a group have chosen to have a formal structure, including leaders, or that traditionally the group take collective decisions on issues that affect the whole group, that the group is somehow vulnerable because economically or culturally disadvantaged or ethnically distinctive, or, finally, identifiable in such a way that the research results may be thought to apply to the group generally. Moreover, the policies lay out different types of group involvement, and it is a matter of debate as to which type of group involvement is the most appropriate.

## ***2. Autonomy and remuneration of the research participants***

The permissibility of financial incentives to “compensate” donors for their participation in genetic research is controversial. At stake is the participant’s autonomy and ability to

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administration through the local assistant chief or the chief . . . In some areas of [Kenya] the permission of the community leaders may be sought where this is necessary”).

<sup>29</sup> NARC, *supra* note 38.

<sup>30</sup> David E. Winickoff, *Biosamples, Genomics, and Human Rights: Context and Content of Iceland’s Biobanks Act*, 4 J. BIOLAW & BUSINESS 11, 13 (2001).

<sup>31</sup> National Council for Science and Technology, *supra* note 34, at 11.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

determine freely whether or not to participate in a research project. The International Declaration on Human Genetic Data of the United Nations Educational, Scientific and Cultural Organization (“UNESCO”) provides that consent shall be “free . . . without inducement by financial or other personal gain.”<sup>34</sup> The majority of guidelines allow the provision of a “*just*” remuneration to research participants.<sup>35</sup> Moreover, gene donors are often prohibited from requesting “a fee for providing a tissue sample, preparation and study of a description of his or her state of health or genealogy, or use of the research results.”<sup>36</sup>

It is problematic to define what a “*just*” remuneration is, i.e., the appropriate yardstick for deciding whether such remuneration is just or not. Often, policymakers limit their analysis to distinguishing between just remuneration and undue influence, recommending that remuneration is just if it does not exert undue influence on potential research participants. Apart from this generic consideration, the guidelines provide little or no guidance in assessing a just remuneration and what *factors* should be taken into consideration.<sup>37</sup> Several guidelines mention the need to reimburse reasonable expenses which the participants incur in donating their samples.<sup>38</sup> Moreover, while reimbursing

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<sup>34</sup> UNESCO 2003, *supra* note 25, at art. 8; *see also*, Council of Europe 2002, *supra* note 25, Art.13 (no “undue influence” shall be exerted); Indian MRC, *supra* note 16, 42 (discussing pedigree studies); National Council for Science and Technology, *supra* note 25, 11.

<sup>35</sup> Tri-Council, *supra* note 26; Isr. 2002, *supra* note 14, at 72.c. Human Genes Research Act, 2000, ¶ 9, 15 (Est.) [hereinafter Est. Act] (the law make it unlawful to “threaten the person with negative consequences, promis[e] material benefits or provid[e] subjective information”).

<sup>36</sup> *Id.* at ¶ 15.

<sup>37</sup> The Tri-Council policy statement recommends that any compensation shall not translate into “undue inducement” by offering incentives that “exceeds the normal range of benefits.” *See*, Tri-Council, *supra* note 26, at 1.5 (the policy however fails to analyze what exceeds the “normal range” of benefits). *See also*, HUGO 1996, *supra* note 28.

<sup>38</sup> Council of Europe, Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine. Explanatory Report ¶ 56 (2000) (“Reimbursement for any expenses or financial loss shall not be regarded as undue influence”) [hereinafter CDBI 2002 Expl. Rep.]; *see also*, Commission de l’éthique de la science et de la technologie, Les enjeux éthiques des banques d’information génétique: pour un encadrement démocratique et responsable (, 2003) (Can.) [hereinafter CEST]; *Model Ethical Protocol for Collecting DNA Samples* (North American Regional Comm., Human Genome Diversity Project), subsequently published in the 33 HOUSTON L. REV. 1431-1473 (1997), *available at* <http://www.stanford.edu/group/morrinst/hgdp/protocol.html> [hereinafter NARC]; Nuffield Council, Human Tissue Ethical and Legal Issues (1995) [hereinafter Nuffield

travel costs is generally considered admissible, lost wages are more controversial.<sup>39</sup> Only the Council for International Organizations of Medical Sciences (“CIOMS”) discusses the baseline for such determination, providing that,

Subjects may be reimbursed for lost earnings, travel costs and other expenses incurred in taking part in a study; they may also receive free medical services. Subjects, particularly those who receive no direct benefit from research, may also be paid or otherwise compensated for inconvenience and time spent. The payments should not be so large, however, or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment.

Council for International Org. of Med. Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002): sub guideline 7 [hereinafter CIOMS].<sup>40</sup>

## **B. Storage**

### ***1. Ownership and commercialization***

Ownership relates to the control over “things,” and it is commonly associated with the ability to use, control, transfer, or otherwise enjoy the owned “thing.” However, whether biological material may be treated as a commodity remains open to debate. Consequently, the status of a right to the ownership of human DNA is controversial. Discussing ownership in the context of genetic databases leads us to reflect upon two issues: (1) the *property* of the collected samples, that of the genetic data that are derived from the samples, that of the information that are part of the database, and that of the database itself, and (2) the permissibility of *commercial transactions* concerning human biological samples.

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Council]. *See also*, U.K. Med. Research Council, Human Tissue and Biological Samples for use in Research - Operational and Ethical guidelines (2001) [hereinafter U.K. MRC].

<sup>39</sup> The Human Genome Organization, Ethics Comm’n, Statement on Benefit-Sharing, sub G (2000) at <http://www.gene.ucl.ac.uk/hugo/benefit.html>: sub G (recommending that reimbursement for “individual’s time, inconvenience and expenses” is permissible) [hereinafter HUGO 2000].

<sup>40</sup> Specific projects, such as the HapMap project, have dealt differently with the remuneration of research participants:

Donors in Nigeria were each given an equivalent of US\$8.00 and multivitamins worth US\$4.00 to compensate them for their time and travel – a standard amount for participation in research involving blood draws in that part of Africa.

...

Prospective donors were not told that they would be compensated until after they had arrived to donate, to guard against the possibility that they would be induced to participate by the prospect of material benefit.

*See*, The International HapMap Consortium, *Integrating ethics and science in the International HapMap Project*, 5 NATURE REVIEW GENETICS 467, 473 (2004).

a) Ownership of samples

Both legislatures and courts are reluctant to recognize the right to own human biological samples.<sup>41</sup> The controversy has a direct impact on biobanks. In fact, biobanking raises the issues of whether samples can be owned, who has *control* over samples, and what are the *rights and obligation* of the entity that controls the samples.

Four views on whether human biological samples can be *owned* are expressed in the policies. Under the first approach, the recipient of the samples becomes their owner. Thus, in Estonia, the law provides that the chief processor becomes owner of “a tissue sample, description of state of health, other personal data and genealogy . . . from the moment the tissue sample or personal data is provided or the moment the state of health or genealogy is prepared.”<sup>42</sup> Similarly, after acknowledging that “[t]he continued absence of clear legal authority admittedly leaves the law uncertain,” Nuffield Council on Bioethics expresses the view that “the user of tissue acquires at least possessory rights and *probably* a right of ownership over tissue once removed.”<sup>43</sup>

Under the second view, the sample sources are the owners of the samples that are transferred to the database.<sup>44</sup> The Tri-Council points out that “[i]t is unethical for a researcher to claim ownership of genetic material by claiming that the concept of private ownership did not exist in the community involved.”<sup>45</sup> Finally, WHO 2003 recommends that “[i]ndividuals are entitled to control over the use of their samples and information, in a manner *akin to* a property right.”<sup>46</sup> Many legal systems, however, reject this view. “Both the common law and the views of many developing countries’ people agree that there is no such thing as property of the body or body parts. Therefore ‘donors’ do not own their genes, or even have that more limited concept, a possessory right in them.”<sup>47</sup>

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<sup>41</sup> Jasper A. Bovenberg, *Inalienably Yours? The new case for an inalienable property right in human biological material: Empowerment of sample donors or a recipe for a tragic Anti-Commons?*, 4 SCRIPT-ED – A JOURNAL OF LAW AND TECHNOLOGY, sub 2 (2004) at <http://www.law.ed.ac.uk/ahrb/script-ed/issue4/bovenberg.asp>.

<sup>42</sup> Est. Act, *supra* note 35, at ¶ 15.

<sup>43</sup> Nuffield Council, *supra* note 38, at ¶ 10.6 (emphasis not in the original).

<sup>44</sup> ASHG 1996, *supra* note 18 (“[b]anked DNA is the property of the depositor unless otherwise stipulated. Therefore, the word ‘donor,’ which implies a gift, is inappropriate”); *similarly*, Isr. 2002, *supra* note 14, at 50 (“the Society is no sense ‘owner’ of the DNA of its individual members. Every individual has full rights on his/her own DNA”).

<sup>45</sup> Tri-Council, *supra* note 26, at 8.8.

<sup>46</sup> WHO 2003, *supra* note 20, at recommendation 2 (emphasis not in the original).

<sup>47</sup> Donna Dickenson, *Consent, Commodification and Benefit-Sharing in Genetic Research*, 4 DEVELOPING WORLD BIOETHICS 109, 121 (2004).

A middle-ground approach is adopted by those guidelines that provide that a biobanker does not become owner of the samples without explicitly discussing who shall be considered owner of the collected samples. Thus, in Iceland, the database controller “shall not be counted as the owner of the biological samples.”<sup>48</sup> To deal with “the legal uncertainty over ownership,” the U.K. Medical Research Council (“U.K. MRC”) uses the term “custodianship” rather than ownership, and recommends “that tissue samples donated for research be treated as gifts or donations, although gifts with conditions attached.”<sup>49</sup> It also considers that the funding body retains ownership of the collection. A similar view is expressed by the French National Ethics Committee, providing that “banking [samples] does not equal to acquiring or owning the collected specimen and the derived data.”<sup>50</sup> Finally, the Royal College of Pathologists acknowledges that “it is . . . unclear whether the tissue becomes the property of those to whom it is given” and concludes that “the hospital or pathologist may be reasonably considered to hold the tissue in trust, primarily for the patient, but also for society at large.”<sup>51</sup> Finally, the Brazilian National Health Committee provides that “the Brazilian researcher and institution will have to be considered as corporate shareholders of the bank [and that consequently] stored samples cannot be considered as exclusive ownership of the country or the institution that hosts the repository.”<sup>52</sup>

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<sup>48</sup> Ice. Act on Biobanks, *supra* note 11, at art. 10.

<sup>49</sup> U.K. MRC, *supra* note 39, at 2.1-2.2.

<sup>50</sup> Comité Consultatif National d'Éthique, Avis et rapport No. 77 (2003) (Fr.), *available at* <http://www.ccne-ethique.fr/francais/avis077.pdf> [hereinafter CCNE].

<sup>51</sup> Royal College of Pathologists, Transitional guidelines to facilitate changes in procedures for handling “surplus” and archival material from human biological samples, 298 (2001), *available at* <http://www.rcpart.org/resources/pdf/transitional.pdf> [hereinafter RCP 2001].

<sup>52</sup> National Health Comm'n, Resolution 347/05: Projects with Use or Storage of Biological Materials, at 5.1 (adopted on 13 January 2005) (Brazil) [hereinafter Brazil NHC 2005].

The final view sees DNA as the common heritage of humanity.<sup>53</sup> The statement on benefit sharing approved by the Human Genome Organization (“HUGO”) specifically refers to the common heritage “that beyond the individual, the family, or the population, there is a common shared interest in the genetic heritage of mankind.”<sup>54</sup> These statements have been interpreted as rejecting samples sources’ claim to be remunerated for consenting to transfer samples taken from them in the databases,<sup>55</sup> as making a case for open access to human genetic databases,<sup>56</sup> and as foundation for benefit sharing.<sup>57</sup> However, the implications one should draw from these statements as to ownership remain unclear. In conclusion, ethical and legal claims that human samples and DNA may be “owned” are controversial and unresolved in the compared policies.

To sum up, the relationship between the manager’s control and the participant’s right of withdrawing the samples and the related data is challenging both from a theoretical and a policy perspective. The policy aspects of withdrawal of consent and of its implications on the storage and use of samples are discussed later in the paper.<sup>58</sup>

b) Control and transfer of samples

The comparative analysis shows a consensus that *control* over DNA samples should rest with the entity that manages the database, which is referred to by different terms:

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<sup>53</sup> HUGO 1996, *supra* note 28; HUGO 2000 *supra* note 39; United Nations Educational, Scientific and Cultural Organization, The Universal Declaration on the Human Genome and Human Rights, art. 4 (1997), *available at* [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=2228&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=2228&URL_DO=DO_TOPIC&URL_SECTION=201.html) [hereinafter UNESCO 1997] (provides explicitly that “the human genome in its natural state shall not give rise to financial gains”); RMGA, *supra* note 17 (talking about the “universality of the human genome”); CCNE, *supra* note 50, at 30 (“the genome is part of the “common heritage, if not of humanity, at least of groups of populations”); *see also*, Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (1997) [hereinafter CHRB]; CDBI Exp. Rep., *supra* note 38; Swed. Biobanks Act 2002, *supra* note 8; NARC, *supra* note 38; Declaración de Manzanillo, *supra* note 5, at second (“the human genome if part of the common heritage of humanity [must be seen] as a reality and not merely as a symbolic statement”).

<sup>54</sup> HUGO 2000, *supra* note 39.

<sup>55</sup> Kare Berg, *The ethics of benefit sharing*, 59 CLINICAL GENETICS 240, 242 (2001).

<sup>56</sup> The Human Genome Organization, Ethics Comm’n, Statement on Human Genomic Databases, *at* <http://www.gene.ucl.ac.uk/hugo/patent.html> [hereinafter HUGO 2002] (“All humans should share in and have access to the benefits of databases”).

<sup>57</sup> HUGO 2000, *supra* note 39.

<sup>58</sup> *See infra*, II.B.3.

custodian, public trustee, user, depositor, and steward. However, several guidelines specify that the institution, rather than the researcher who is affiliated with the institution, should retain control. In the guidelines, control rights often substantiate into the rights to have exclusive possession and to use and manage samples and data. The prerogatives are summed up by the Nuffield Council: “. . . a hospital which has tissue in its possession . . . has such property rights over the tissue as to exclude any claim of another to it [and] recover the tissue if it were taken without permission.”<sup>59</sup>

Due to the public interest attached to using human biological samples in biomedical research, the policies assign a number of *obligations* to the “manager” of the collection. The “manager” has a duty to “balance conservation against distribution to research collaborators,”<sup>60</sup> to manage samples and derived, genetic data properly,<sup>61</sup> to “safe keeping samples and controlling their uses [and to] facilitate optimum usage,”<sup>62</sup> to “promote [and] perform” genetic research,<sup>63</sup> to decide “what happens to collection after project is completed.”<sup>64</sup> Finally, the manager’s exclusive right to control the samples also creates the obligation to store the samples “in such a way that they are not lost or damaged, and that they are not accessible to those who are not entitled to use them,”<sup>65</sup> and to keep “proper records of uses.”<sup>66</sup>

When it comes to the transfer of samples and data, several policies impose restrictions. First, *territorial limitations* to the circulation of samples are also controversial. On one hand, the view that biomedical research serves the public good, and that exchange of information has to be encouraged as much as possible, is widely accepted.<sup>67</sup> On the other hand, other policies recommend, or even make it unlawful, to transfer samples outside a

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<sup>59</sup> Nuffield Council, *supra* note 38, at ¶ 10.6.

<sup>60</sup> *Data storage and DNA banking: Technical, Social and Ethical Issues. Recommendation of the European Society of Human Genetics*, 11 EUROPEAN SOCIETY OF HUMAN GENETICS S8=S10 (Supp. 2 2002) [hereinafter ESHG 2002].

<sup>61</sup> CCNE, *supra* note 50.

<sup>62</sup> U.K. MRC, *supra* note 39, at 9.2.

<sup>63</sup> Est. Act, *supra* note 35, at ¶ 3.

<sup>64</sup> *Id.*

<sup>65</sup> Ice. Act on Biobanks, *supra* note 11, at art. 8.

<sup>66</sup> U.K. MRC, *supra* note 39, at 9.4.

<sup>67</sup> The UNESCO International Declaration of Human Genetic Data provides a clear illustration of this approach:

States should regulate . . . the cross-border flow of human genetic data, human proteomic data and biological samples so as to foster international medical and scientific cooperation and ensure fair access to this data.

UNESCO 2003, *supra* note 25, at art. 18(a).

specific country.<sup>68</sup> Other policies limit the circulation based on the view that confidentiality cannot be protected once samples leave the country.<sup>69</sup> In other cases, the policies prevent the transfer of the entire database on foreign soil.<sup>70</sup> Second, several policies provide that samples that are transferred to *third-parties* (a different biobank or other investigators) may not be handed out further.<sup>71</sup> In Iceland, the licensee may not “pass the biological samples on to another party.”<sup>72</sup> The issue is particularly relevant in the case of international collaboration. Finally, other policies prevent *commercial companies* from accessing samples.<sup>73</sup>

Creating *networks or consortia* of investigators, who sign up to contractual policies that govern access to a common repository or a series of collections that are shared within the network, is increasingly thought to be a viable way to address some of the concerns arising out of an unregulated circulation of samples and data.<sup>74</sup> An alternative is also to make samples fully accessible and/or to put all research findings in the public domain, for instance by submitting them to a public accessible genetic databank.<sup>75</sup>

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<sup>68</sup> In Estonia, “the chief processor cannot transfer samples and uncoded information” and “all tissue samples shall be stored in the territory of the Republic of Estonia. *See*, Est. Act, *supra* note 35, at ¶ 15, 18. *See also*, Human Genome Research Law, section 15.2-3 (Adopted by Latvian Parliament Saeima on June 13, 2002 and proclaimed by President of Latvia on July 3, 2002) [hereinafter Lat. Law] (“The gene donor has no rights to request a payment for the transfer of tissue samples”). In Sweden, “[a] biobank or parts thereof must not be transferred to a recipient in another country.” *See*, Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 7. In Brazil, investigators must show why the samples need to be transferred outside the country. *See*, Brazil NHC 2004, *supra* note 22, at Iv.1.1.

<sup>69</sup> The Council of Europe provides that source countries may transfer human biological materials and personal data to another state “only . . . if that state ensures equivalent levels of protection.” CDBI 2002 Expl. Rep., *supra* note 38, at art.8.

<sup>70</sup> Isr. 2002, *supra* note 14, at 50 (against the transfer of public DNA sample collections genetic databases). The same policy however contemplates that transferring such collections because “it may be decided to negotiate deals with a multinational or foreign company in order to develop specific research projects and/or products. *Id.* at 55.a.

<sup>71</sup> Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 2.

<sup>72</sup> Ice. Act on Biobanks, *supra* note 11, at art. 10.

<sup>73</sup> Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 8; NARC, *supra* note 38.

<sup>74</sup> Robin Fears and Gerge Poste, *Building Population Genetics Resources Using the U.K. NHS*, 284 *SCIENCE* 267 (1999).

<sup>75</sup> Examples of such networks are the SNP Consortium (<http://snp.cshl.org>), the Expression Projects for Oncology (<http://snp.cshl.org>), and the Prostate SPORC National Biospecimen Network (<http://prostatenbnpilot.nci.nih.gov/default.asp>).

c) Commercialization

In general, owners of objects or commodities may earn a profit by transferring their rights to third parties. Should the individuals who provide samples to a database be compensated for providing biological material? Should the entities that have control over stored tissue samples be able to transfer them to third parties in exchange of money? Should commercial companies have access to human genetic databases, whether or not by paying a fee?

The commodification of human biological samples is ethically controversial and the answer to these questions lies in an intertwined combination of moral and legal judgments that often exceed the scope and the aims of the policies that we are comparing in this study. A few policies provide some general statements and practical guidance to address the issue of commodification of DNA.<sup>76</sup> The Universal Declaration on the Human Genome states that “the human genome in its natural state shall not give rise to financial gains.”<sup>77</sup> Many interpretations have been given to this and similar policy statements. Berg argues from it that samples sources’ may not be remunerated for consenting to transfer samples taken from them in the databases.<sup>78</sup> The issue has been explored while discussing the respect of autonomy of research participants and their remuneration for participating as “undue influence.”<sup>79</sup> Others argue that the prohibition of financial gains implies that no fee to access samples is permissible.<sup>80</sup> On the issue of whether a biobank can sell stored samples, no guideline goes as far as explicitly granting the right of one database controller to sell the samples or the data to third parties.

Several policies acknowledge the potential *commercial uses* of samples and genetic data.<sup>81</sup> The Tri-Council specifies that “at the outset of a research project, the researcher

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<sup>76</sup> Declaración de Manzanillo, *supra* note 5, at sixth, a (stressing “the need to prohibit the ‘comercialización’ [commercialization] of the human body, its parts and their products”).

<sup>77</sup> UNESCO 1997, *supra* note 53, at art. 4; *see also*, CDBI 2002 Expl. Rep., *supra* note 38, at art.8; CHRB, *supra* note 53; NARC, *supra* note 38.

<sup>78</sup> Berg, *supra* note 55, at 242. *See also*, Lat. Law, *supra* note 68, at 11.2 (“The gene donor has no rights to request a payment for the transfer of tissue samples”).

<sup>79</sup> *See supra*, II.A.2.

<sup>80</sup> Daryl Pullman & Andrew Latus, *Policy Implications of Commercially Sponsored Human Genetic Research in Newfoundland and Labrador. A report for the Newfoundland and Labrador Department of Health and Community Services* 38 (2003) at <http://www.uccs.mun.ca/~alatus/benefitssharing/FinalReport.pdf> (“For example, research may focus on genetic causes of obesity rather than on causes stemming from diet or lifestyle . . . In addition . . . commercial pressures may corrupt the research process itself”).

<sup>81</sup> CEST, *supra* note 38; Tri-Council, *supra* note 26, at art. 8.7; ESHG 2002, *supra* note 60.

shall discuss with the [Research Ethics Boards] and the research subject the possibility and/or probability that the genetic material and the information derived from its use may have potential commercial uses.”<sup>82</sup> Database *access by commercial entities* is also controversial. Several policies prevent third-party access for commercial purposes.<sup>83</sup> Critics of commercial access have argued that commercialization could bias or even corrupt genetic researchers.<sup>84</sup>

By contrast, other policies state that access to collections by commercial companies is admissible.<sup>85</sup> Notably, the U.K. MRC permits only access to data and not to samples. Indeed, the practical arrangements of research projects vary. “[I]n the Singapore and CARTaGENE projects, there is no anticipation of corporate involvement or financial gain.”<sup>86</sup> Conversely, the biobanking projects in Estonia, Iceland, Latvia and Sweden are (or, were) expected to lead to profit-making.<sup>87</sup> Notably, both in Iceland and Sweden commercial entities are granted “exclusive rights to national medical and genetic data.”<sup>88</sup> It seems also uncontroversial that, if it is foreseeable that samples and data could be used by commercial companies, participants must be informed at the time the samples were collected or whenever re-consenting to uses that were not laid down in the consent form at the time the samples were taken.<sup>89</sup>

## 2. *Identifiability*

The protection of identifiable health and genetic information and the implications of linking genetic data to other sensitive personal information are delicate matters. The ability to link human biological samples and genetic data to other sources of data make biobanks tremendously powerful research tools. Like other types of medical information, human genomic data are sensitive and raise concerns about discrimination and stigmatization, which may materialize in the loss of insurance or employment for

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<sup>82</sup> Tri-Council, *supra* note 26, at art. 8.7; Isr. 2002, *supra* note 14, at 57-58.

<sup>83</sup> Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 8; NARC, *supra* note 38.

<sup>84</sup> Pullman & Latus, *supra* note 80, at 17.

<sup>85</sup> WHO 1997, *supra* note 10, at 13 (“possible sharing . . . including . . . commercial entities”); U.K. MRC, *supra* note 39, at 4.5; CEST, *supra* note 38, at 48; Tri-Council, *supra* note 26; ESHG 2002, *supra* note 60; Nuffield Council, *supra* note 38; Est. Act, *supra* note 35; MINISTRY OF EDUCATION, CULTURE, SPORTS, SCIENCE AND TECHNOLOGY, MINISTRY OF HEALTH, LABOUR AND WELFARE, AND MINISTRY OF ECONOMY, TRADE AND INDUSTRY, ETHICS GUIDELINES FOR HUMAN GENOME/GENE ANALYSIS RESEARCH (2001) (Japan) [hereinafter Japanese Guidelines]; CCNE, *supra* note 50; HGC, *supra* note 13.

<sup>86</sup> Austin et al., *supra* note 4, at 43.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> S. Orr et al., *supra* note 5; Isr. 2002, *supra* note 14, at 72.a.

individuals whose samples have been collected and processed and their relatives. Thus, the collection of human DNA poses privacy challenges.<sup>90</sup>

From an ethical point of view, the right of the individual that information about him/her is kept confidential and only divulged to others with his/her consent is commonly derived from the principle of respect for persons' autonomy.<sup>91</sup> Also the need to avoid (a risk of) stigmatization is cited as rationale to establish mechanisms to de-identify samples and data.<sup>92</sup> Practical reasons further support protecting participants' confidentiality. In fact, it is in the interest of research that confidentiality be granted because the public needs confidence to participate in research activities. Therefore, "policies protecting privacy and confidentiality in research . . . are essential not only to protect individuals but to ensure the advancement of science."<sup>93</sup>

All guidelines that discuss the issue agree that some mechanism to ensure the protection of confidentiality is required. Thus, most policies require that appropriate institutions be in place to implement measures for the protection of individuals' privacy and the confidentiality of the collected, linked data. Nevertheless, the policies disagree on *what are the best measures* to ensure full protection of the confidential information, on *what shall be protected as confidential*, and on the *nomenclature* of the different arrangements.

a) Measures to protect confidentiality

Although generally inclined towards requiring some form of anonymization, the guidelines differ widely on what practical measures should be taken. Three arrangements are possible: anonymous samples and data, identified samples and data, and anonymized yet linkable samples and data. *Anonymity* of samples and data is often disfavored because it reduces the range of opportunities available to investigators research and prevents participants from being re-contacted in future. Thus, stripping all identifiers is very often ruled out because "retaining identifiers . . . will permit more effective biomedical research and the possibility of re-contacting the subject when therapeutic option becomes available."<sup>94</sup> Because of the nature of project (developing "a haplotype map of the human

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<sup>90</sup> M.R. Anderlik and M.A. Rothstein, "Privacy and confidentiality of genetic information: what rules for the new science?" *Annual Review Genomics and Human Genetics* 2 (2001): 401-33, 401.

<sup>91</sup> Tri-Council, *supra* note 26, at art. i.5 ("[r]espect for human dignity also implies the principles of respect for privacy and confidentiality"); National Council for Science and Technology, *supra* note 34, at 11; *see also*, S. Orr et al., *supra* note 5, at 8-9.

<sup>92</sup> Brazil NHC 2004, *supra* note 22, at III.2; Isr. 2002, *supra* note 14, at 71.b.

<sup>93</sup> Editorial, "Protecting individuals and promoting science," *Nature Review Genetics* 28, no. 3 (2001): 195-6.

<sup>94</sup> ESHG 2002, *supra* note 60, at 10; The Human Genome Organization, Ethics Comm'n, Statement on DNA Sampling: Control and Access, at <http://www.gene.ucl.ac.uk/hugo/sampling.htm> (1998) [hereinafter HUGO 1998]

genome [and] describe the common patterns of human DNA sequence variation), the HapMap investigators have chosen complete anonymization.<sup>95</sup> Moreover, one could argue that truly anonymous biological samples do not exist. In fact, Lin et al. have shown that “[i]f someone has access to individual genetic data and performs matches to public SNP data, a small set of SNPs could lead to successful matching and identification of the individual.”<sup>96</sup> Truly anonymous would then only be “archeological” tissue samples, for which no material for comparison to an identified person exists. Another option that is generally ruled out on confidentiality grounds is the store and use *identified* samples and data.

Between the two extremes, samples and data that were not anonymously collected may be *anonymized*. Coded samples and data belong to this category. The UNESCO International Declaration on Human Genetic Data provides that genetic data “should not normally be linked to an identifiable person,”<sup>97</sup> and policies around the world commonly agree with this recommendation.<sup>98</sup> Although this solution is favored by almost all

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(“careful consideration should be given before proceeding to strip samples of identifiers since other unknown, future uses may thereby be precluded as well as may the validation of results”); Tri-Council, *supra* note 26, at art. 3.2 (“[a]s a general rule, the best protection of the confidentiality of personal information and records will be achieved through anonymity”); HEALTH SCIENCE INFORMATION BANKS – BIOBANKS 6 (Forskningsstyrelsen [Danish Research Agency], 1996), at [http://forsk.dk/portal/page?\\_pageid=407,1041249&\\_dad=portal&\\_schema=PORTAL&\\_calledfrom=2](http://forsk.dk/portal/page?_pageid=407,1041249&_dad=portal&_schema=PORTAL&_calledfrom=2) (recommending that “[w]henver possible, complete *anonymisation* should be adopted, or alternatively encryption”) (emphasis in the original) [hereinafter Denmark].

<sup>95</sup> The International HapMap Consortium, *supra* note 40, at 471 (samples were collected with population and sex identifiers, but without links to individual donors so that “it will be extremely difficult for anyone to link any genomic data in the HapMap database to a specific person”).

<sup>96</sup> Zhen Lin et al., *Genomic Research and Human Subject Privacy*, 305 SCIENCE 183 (2004).

<sup>97</sup> UNESCO 2003, *supra* note 25, at art. 14(c). *See also*, U.K. MRC, *supra* note 39, at 13; RMGA *supra* note 17; CCNE, *supra* note 50, at 20 (“Protection of the anonymity of the samples is necessary by adopting coding procedures that have been developed nowadays”); NBAC, *supra* note 18, at recommendation 10; HGC, *supra* note 13, at 5.13 (“... satisfactory techniques of encryption be used whether the anonymization is to be reversible”); Brazil NHC 2005, *supra* note 52, at 2.2.

<sup>98</sup> Est. Act, *supra* note 35, at ¶ 20 (“tissue samples, descriptions of DNA and descriptions of state of health” are coded, except upon the issue of data on a gene donor to the gene donor or to the doctor of the gene donor”); Japanese Guidelines, *supra* note 85, at rule 5(6), subrule 6(6) (the principal investigator “shall, in principle, conduct human genome/gene analysis research by using anonymized human specimens or genetic information,” and anonymization is not required only if the donor consents and the research protocol is authorized by the ethics review committee and approved

policies, disagreement exists on what *measures* must be implemented to protect the research participants' privacy, although the majority of guidelines recommend some degree of anonymization. One approach is to require investigators to introduce "as many disconnects between the identity of donors and the publicly available information and materials as possible."<sup>99</sup> The goal is to prevent anyone "to establish that a specific DNA sequence came from a particular individual, other than re-sampling an individual's DNA and comparing it to the sequence information in the public database."<sup>100</sup> Moreover, it recommends establishing "gene libraries that contain 'mosaics' or a 'patchwork' of sequenced regions derived from a number of different individuals, rather than of a single individual"<sup>101</sup> It is however controversial whether an *independent body* rather than the investigators or the collecting physicians must hold the code linking the randomized number assigned by the project to data and biological specimens of each participant and the personal nominative data of the participant.<sup>102</sup> Some projects, such as the CARTaGENE project, adopted a double coding strategy where the holder of the code, linking the randomized number assigned by the project to data and biological specimens of each participant and the personal nominative data of the participant, to an independent body.<sup>103</sup> Support for the involvement of an independent body is found in the need to

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by the director of a research institution"); Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 10 ("if the personal data regarding a donor is disclosed at the same time as a coded tissue sample from the same donor is handed out, the delivery shall be made in such a manner that the personal data cannot be connected with the tissue sample").

<sup>99</sup> U.S. NATIONAL CENTER FOR HUMAN GENOME RESEARCH, AND U.S. DEPARTMENT OF ENERGY, NCHGR-DOE GUIDANCE ON HUMAN SUBJECTS ISSUES IN LARGE-SCALE DNA SEQUENCING: EXECUTIVE SUMMARY [AND] EXECUTIVE SUMMARY OF JOINT NIH-DOE HUMAN SUBJECTS GUIDELINES (1996), *at* <http://www.nhgri.nih.gov/10000921> [hereinafter NCHGR-DOE].

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> Isr. 2002, *supra* note 14, at 71 (the "participating physicians" are the code holders); Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 10 ("physicians assigns and keep the code"); Lat. Law, *supra* note 68, at 4.1-2 (the coding is done by the "chief processor" who is *inter alias* responsible for performing "the genetic research and to collect, store, destroy or issue genetic data"). *But see*, WHO 2003, *supra* note 20, at recommendation 7 ("any anonymisation process be overseen by an independent body"); Est. Act, *supra* note 35, at ¶ 23 ("the chief processor may give an additional code to a coded tissue sample, coded description of DNA, coded description of state of health or coded genealogy"). In Denmark, the guidelines recommend that a "third and independent party" shall have a broader role than merely holding the key to re-identify samples and data in the overall governance structure of a biobank. *See*, Denmark, *supra* note 94.

<sup>103</sup> Memorandum from the CARTaGENE Project, Update of the CARTaGENE Project (November 15, 2003): 1 (on file with the author).

“scrutinise and ensure the legitimacy of requests to the database . . . to act . . . as an intermediary between the creators and the users of the database [and to] maintain standards and keep anonymisation processes under review.”<sup>104</sup> A different strategy is adopted in Iceland, where samples and data are unidirectionally encrypted yet identifiable. Thus, personal information “shall be coded before entry on the database . . . Personal identification shall be coded one-way, i.e. by coding that cannot be traced using a decoding key.”<sup>105</sup>

b) What shall be protected as confidential?

Policies differ greatly on defining what kind of information shall be kept confidential. The policies can be divided in four groups depending on the type of information that is protected: genetic data in general, genetic data linked to an identifiable person, the identity of the research participants, and other information. Besides the varying terminology,<sup>106</sup> policymakers disagree on whether confidentiality shall extend to the *samples*, the *data*, and/or the *personal information* collected in the course of genetic research.

A first group of policies provides that *genetic data* shall be kept confidential.<sup>107</sup> Moreover, College of American Pathologists provides that genetic information should be subjected to “the same standards of privacy, confidentiality, and security as nongenetic medical information.”<sup>108</sup> Other policies provides that *genetic data that are linked* to an identifiable person shall be kept confidential. Thus, UNESCO 1997 limits the scope of protection to the following: “[g]enetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose.”<sup>109</sup> On similar lines, the UNESCO International Declaration on Human Genetic Data provides that confidentiality extends to “(a) . . . human genetic data linked to an identifiable person, a family or, where appropriate, a group [and to] (b) [h]uman genetic data, human proteomic data and biological samples linked to an identifiable person.”<sup>110</sup> A third group of

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<sup>104</sup> WHO 2003, *supra* note 20, at recommendation 7.

<sup>105</sup> Act on a Health Sector Database, No. 139/1998 (Iceland), at art. 7.

<sup>106</sup> To a certain extent, the guidelines merely differ because they use a different terminology to refer to identical information.

<sup>107</sup> WHO 1997, *supra* note 10, at ii (“genetic data”); CEST, *supra* note 38, at 37 (“information”); ESHG 2002, *supra* note 60, at 18 (“genetic information”); Declaración de Manzanillo, *supra* note 5, at fifth, a; HUGO 1996, *supra* note 28 (“privacy and protection against unauthorized access be ensured by the confidentiality of genetic information”).

<sup>108</sup> RCP, *supra* note 51, at 297.

<sup>109</sup> UNESCO 1997, *supra* note 53, at art. 7.

<sup>110</sup> UNESCO 2003, *supra* note 25, at art. 14; ASHG 1996, *supra* note 18 (providing that “[s]tudies that maintain identified or identifiable specimens must maintain subjects’

guidelines affords a more confined protection of confidentiality, i.e., the *identity* of the sample sources.<sup>111</sup> For instance, the law in Estonia limits the protection to the “identity of gene donors” and that researchers “shall maintain the confidentiality of the identity of the gene donor, his or her tissue sample, the description of his or her state of health and his or her genealogy.”<sup>112</sup> Finally, other policies extend the notion of confidentiality to *information other than genetic data and/or the identity* of the research participants. The scope of the protection of confidentiality thus ranges from “[the] complete records of the sampling process, including the identities of individual donors,”<sup>113</sup> to “genetic material and information [and to the] identity of the participants,”<sup>114</sup> or, more broadly, to “all personal and medical information relating to research participants . . . results of laboratory tests . . . and information obtained directly from donors or from their medical records.”<sup>115</sup>

Policies often do not construe the duty to protect confidentiality as an absolute one. The guidelines differ, however, in providing *limitations* to the general rule that sample, data and/or identity shall be kept confidential. Whereas no guideline explicitly provides that limitations are not permissible, several guidelines state that the duty to maintain confidentiality is not an absolute one. The policies list different *sources* of limitations to confidentiality: the law, the power of governmental agencies, public international law and international human rights law, or finally the participant’s consent. Moreover, the guidelines list different grounds for limitations to confidentiality, ranging from the public

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confidentiality” and later specifying that “[i]nformation from these samples” shall be disclosed to third parties only the samples source’s previous authorization in writing.)

<sup>111</sup> GNEC, *supra* note 8, at 66 (situations in which “the research workers engaged on a project know or can discover donors’ identities” trigger confidentiality obligations); Ice. Act on Biobanks, *supra* note 11, at art. 10 (confidentiality extends to “connecting data from the health-sector database, from a database of genealogical data, and from a database of genetic data”); National Council for Science and Technology, *supra* note 34, at 11; *see also*, S. Orr et al., *supra* note 5 (“the records in which the subject is identified must be kept confidential”).

<sup>112</sup> Est. Act, *supra* note 35, at ¶¶ 11, 14. Similarly, the Swedish law provides that “personal data regarding a donor” must be kept confidential. *See*, Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 10; Lat. Law, *supra* note 68, at 13.5.

<sup>113</sup> NARC, *supra* note 38, at D.

<sup>114</sup> RMGA, *supra* note 17.

<sup>115</sup> U.K. MRC, *supra* note 39, at 4 (talking about “private personal genetic information” and “medical information, and some other forms of information”); *Statement on storage and use of genetic materials*, 57 AM. J. HUM. GENETICS 1499-1500 (1995) (statement by the American College of Med. Genetics, Storage of Genetics Materials Comm. Statement) [hereinafter ACMG]; Indian MRC, *supra* note 16, at 41-42 (emphasizing that “diagnosis . . . medical or personal information about individuals to other family members” must not be revealed); Denmark, *supra* note 94.

interest to an overriding interest of a third-party, i.e. blood relatives, family members, or to the interest of the patient herself.

c) Nomenclature

The *language* used by policies to refer to research samples is a source of substantial confusion.<sup>116</sup> Surveying the terminology of confidentiality mechanisms in several policies, Knoppers and Saginur found a “proliferation of a bewildering array of terminologies at the national and international levels.”<sup>117</sup> The differences between European and North American policies are great,<sup>118</sup> and this “babelesque” terminology is even more acute if we consider that investigators from different countries shall refer policies in a foreign language or translated into English from a foreign language. This confusion may be a practical barrier to international collaboration, especially if one considers that the ethical review of research protocols may involve analyzing the state of confidentiality mechanisms in a different country.

What emerges from the comparative analysis of the guidelines is that most of them require some form of anonymization, which in general substantiate in storing coded samples and in providing them to investigators in an anonymous fashion. Whether the code holder must be an independent body is unsettled. Irreversible anonymization is commonly not favored, and, if it is recommended, investigators are often required to support their choice on scientific grounds.<sup>119</sup> The value of research collections is in fact “significantly increased if all the data relating to the samples are stored together and made available in an anonymised form to all users.”<sup>120</sup> There is also consensus that participants must be informed how confidentiality is protected, including in which form biological samples are stored and used by accessing researchers. In fact, several guidelines point out that before consenting donors have the right to know about the arrangements made concerning confidentiality.<sup>121</sup> Finally, it is very important to reach some harmonization as to the nomenclature of the various mechanisms to protect confidentiality.

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<sup>116</sup> Godard et al., *supra* note 4, at S90-S91.

<sup>117</sup> Bartha Maria Knoppers & Madelaine Saginur, *The Babel of genetic data terminology*, 23 NATURE REVIEW BIOTECHNOLOGY: 925, 925 (2005) (proposing a simplified nomenclature for sample identifiability.)

<sup>118</sup> CDBI 2002 Expl. Rep., *supra* note 38, at art. 2 (distinguishing between anonymous, anonymized – linked and unlinked samples – coded, and identified samples); NBAC, *supra* note 18 (distinguishing between unidentified, unlinked samples, coded samples, and identified samples, where “coded” comprises both what the Council of Europe calls “unlinked” samples and “coded” samples).

<sup>119</sup> Brazil NHC 2004, *supra* note 22, at III.8-9.

<sup>120</sup> U.K. MRC, *supra* note 39, at 5.5.

<sup>121</sup> *See, e.g.*, Brazil NHC 2004, *supra* note 22, at IV.1.h.

### 3. *Withdrawal of consent*

The right to withdraw consent is closely linked to the protection of autonomy through a consent procedure that respects research participants. The Declaration of Helsinki provides that “[t]he subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal.”<sup>122</sup> While the policies agree that some form of consent is necessary in order to collect, store and use human biological samples, the issue of the withdrawal of consent is more controversial. In the next paragraphs, we will focus our analysis on the how the policies frame and put into practice the right of withdrawal of consent.

#### a) *Framing the right to withdraw consent*

The overwhelming majority of guidelines grant research participants the right to withdraw their consent. The CIOMS guidelines provide that “. . . the individual is free to . . . to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled.”<sup>123</sup> Similarly, a right of withdrawing consent is *recognized* by several other guidelines,<sup>124</sup> and by the national laws in Estonia,<sup>125</sup> Iceland,<sup>126</sup> Latvia,<sup>127</sup> and Sweden.<sup>128</sup>

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<sup>122</sup> WORLD MED. ASS’N, DECLARATION OF HELSINKI: RECOMMENDATIONS GUIDING PHYSICIANS IN BIOMEDICAL RESEARCH INVOLVING SUBJECTS, 22 *available at* <http://www.wma.net/e/policy/pdf/17c.pdf>.

<sup>123</sup> CIOMS, *supra* note 26, at guideline 5.

<sup>124</sup> CHRIB, *supra* note 53, at art. 16 (“consent may be freely withdrawn at any time”); CDBI 2002 Expl. Rep., *supra* note 38, at art.15.2 (“Information given at time of consent may include “[t]he right to withdraw consent at any time”); UNESCO 2003, *supra* note 25, at art. 9; CEST, *supra* note 38, at 48; Tri-Council, *supra* note 26, at art. 2.2 (“Consent must be freely given and may be withdrawn at any time”); RCP, *supra* note 51, at 52; HUGO 1998, *supra* note 94 (“the possibility of withdrawal of consent to participate without prejudice [is] an ethical prerequisite”); Japanese Guidelines, *supra* note 85, at rule 8; ESHG 2002, *supra* note 60; NARC, *supra* note 38 (“As in other research, the HGD Project must allow participants to withdraw from the research”); RMGA, *supra* note 17 (“the participant should be able to withdraw from the research project at all times”); WHO 2003, *supra* note 20, at recommendation 18 (“. . . information, and any personally identifiable samples also held, should be destroyed on the request of the subject”); ACMG, *supra* note 115, at II, A; National Council for Science and Technology, *supra* note 34, at 12; Brazil NHC 2004, *supra* note 22, at III.7.

<sup>125</sup> Est. Act, *supra* note 35, at ¶ 10.

<sup>126</sup> Ice. Act on Biobanks, *supra* note 11, at art. 7.

<sup>127</sup> Lat. Law, *supra* note 68, at 11.1.3.

Most guidelines recognize a right of withdrawal, yet critiques of the dominant view are not absent. Although recognizing that international and national guidelines on the use of human subjects in research have stressed the research participants' right to withdraw from a study at any time and for any reason, the U.K. Human Genetics Commission points out that "[t]he same right has not been as clearly established in cases where participation is limited to the donation of bodily materials."<sup>129</sup> Since future research on samples does not have any physical impact on the donors, the U.K. Human Genetics Commission judges the right to withdrawal to be less obvious or less morally required than in classical research involving human subjects. When donating his/her sample, the participant "forego[es] any further claim on the sample." In addition, a right to withdrawal could "compromise research progress if samples were reclaimed after significant work had been done on them." Accordingly, the U.K. Human Genetics Commission considers that the right to withdraw "might depend on the nature of the research involved," and recommends that the consent document should "clearly specify the arrangements for withdrawal from the study and the subsequent fate of samples and data."<sup>130</sup>

On the other hand, WHO 1997 do not explicitly grant a right of withdrawal, and the pervasive rationale behind the guidelines suggests that it is unlikely to be available. In fact, the guidelines recommend that "[c]ontrol of DNA may be familial, not only individual [and] DNA should be stored as long as it could be of benefit to living or future relatives of fetuses."<sup>131</sup>

b) Implementing the withdrawal of consent

The implementation of the exercise of the right of withdrawal is problematic from a practical, rather than theoretical, point of view. First, several guidelines recommend *destroying the biological sample and removing all data*.<sup>132</sup> Thus, WHO 2003 recommends, "[p]ersonally identifiable information held on a database . . . and any personally identifiable samples also held, should be destroyed on the request of the subject."<sup>133</sup> Also the Council of Europe Draft Explanatory Report recommends that "[t]he individual has the right to withdraw from the research and the right to destruction of human biological materials and data."<sup>134</sup>

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<sup>128</sup> Swed. Biobanks Act 2002, *supra* note 8, at chapter 3, sect. 6.

<sup>129</sup> HGC, *supra* note 13, at 95.

<sup>130</sup> *Id.* at 96.

<sup>131</sup> WHO 1997, *supra* note 10, at 13.

<sup>132</sup> Lat. Law, *supra* note 68, at 11.1.3 ("the description of state of health of the gene donor and any information related to the identification of a person shall be destroyed").

<sup>133</sup> WHO 2003, *supra* note 20.

<sup>134</sup> CDBI 2002 Expl. Rep., *supra* note 38, at art.16.

A second policy option is allowing *the destruction of the samples but not the derived data*. In Iceland, “[a] donor of a biological sample can at any time withdraw his/her consent . . . and the biological sample shall then be destroyed.”<sup>135</sup> However, if the human biological samples are collected during clinical testing and treatment where “assumed consent” rule operates, donors may opt out and their samples cannot be destroyed but can “only be used in the interest of the donor,” thus excluding using them in research.<sup>136</sup> Moreover, the Director General of Public Health is responsible for including the donor’s name on a list of people who have opted out and make it available to various institutions and health care professionals. Finally, HUGO recommends that stored samples are destroyed at the specific request of the person unless there is a need for access by immediate relatives.<sup>137</sup> The Committee’s statement also points out that ongoing studies are not affected by the withdrawal.<sup>138</sup>

Third, although providing for the destruction of the samples, other policies are *unclear or silent* on whether the withdrawal affects also the derived data that are stored in the database. In Sweden, “[i]f the withdrawal refers to every use the tissue sample must immediately be destroyed or de-personalised.”<sup>139</sup> The European Society of Human Genetics recommends the “destruction of [the donors’] sample” without further specification.<sup>140</sup>

Other guidelines opt for a fourth solution: the *destruction of the link between the code and the stored sample*. In Estonia, “gene donors have the right to apply, at any time . . . for the destruction of data which enables decoding.”<sup>141</sup> However, the law also provides that “[i]f the identity of a gene donor is unlawfully disclosed, the gene donor has the right to apply to the chief processor for the destruction of the tissue sample, description of DNA and description of the state of health pursuant to the provisions of § 21 of this Act.”<sup>142</sup> We have also seen that in Sweden depersonalized samples may be used in research despite the withdrawal.<sup>143</sup>

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<sup>135</sup> Ice. Act on Biobanks, *supra* note 11, at art. 7.

<sup>136</sup> *Id.*

<sup>137</sup> HUGO 1998, *supra* note 94.

<sup>138</sup> *Id.*

<sup>139</sup> Swed. Biobanks Act 2002, *supra* note 8, at chapter 3, sect. 6.

<sup>140</sup> ESHG 2002, *supra* note 60, at 7.

<sup>141</sup> Est. Act, *supra* note 35, at ¶ 10.

<sup>142</sup> *Id.*

<sup>143</sup> Swed. Biobanks Act 2002, *supra* note 8, at chapter 3, sect. 6.

### c) *Limitations*

Although participants may be entitled to withdraw their consent at any time along the research process, destroying the data is impossible once the information derived from the human biological samples falls into the public domain or once is incorporated with other data in a fashion that makes it impossible to isolate the data derived from one specific sample. However, guidelines rarely discuss this circumstance. Among the few policies discussing the issue, the U.S. National Center for Human Genome Research points out that “[i]n the case of donors for large-scale sequencing, it will not be possible to withdraw either the libraries made from their DNA or the DNA sequence information obtained using those libraries once the information is in the *public domain*.”<sup>144</sup> Moreover, the law in Iceland provides that “the results of studies already carried out shall . . . not be destroyed.”<sup>145</sup> The language does not provide much guidance, however, being the notions of “results” and “already carried out” study quite unclear.

The guidelines also fail to address the issue of withdrawal and the blood relatives’ interest. The Tri-Council guidelines simply raise the issues,<sup>146</sup> failing to discuss further its policy implications.

### 4. *Rules for disposal*

Supervening events, such as the bankruptcy of the repository or the samples are of no longer value, may prevent samples from being kept stored any longer. Very few guidelines address the issue. In Sweden, the law requires “to destroy the tissue samples, if the material no longer is of any importance . . . and there are no general interest in keeping the samples.”<sup>147</sup> Moreover, it is in the discretion of the principal of the biobank to decide whether the samples are returned to the care provider or simply destroyed. The U.K. MRC provides that “[i]f samples are no longer of value, they should be disposed of safely and sensitively.”<sup>148</sup> Their disposal should then be carried out in accordance to the provisions laid out in the informed consent form. In discussing commercial collections in Israel, the guidelines provide that “[i]n the event that the commercial company . . . is

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<sup>144</sup> NCHGR-DOE, *supra* note 99 (emphasis added).

<sup>145</sup> Ice. Act on Biobanks, *supra* note 11, at art. 7.

<sup>146</sup> Tri-Council, *supra* note 26, at 8.8 (“Where banking is concerned, withdrawal affects not only the individual but also the biological relatives”).

<sup>147</sup> Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 9.

<sup>148</sup> U.K. MRC, *supra* note 39; Isr. 2002, *supra* note 14, at 65 (“Should the activity on a Public collection be terminated, the DNA samples will be returned by the institution, transferred to a proper deposit place and will remain under the control of the HUGIC Authority”).

closed or sold to a third party, the DNA samples as well as the genetic database will be immediately transferred to the HUGIC Authority.”<sup>149</sup>

On the other hand, some policies allow only the temporary storage of biological samples or only for the time needed to complete the purpose pursued in banking the samples.<sup>150</sup> The Brazilian National Health Committee provides that storage can only be authorized for a period not exceeding 5 years, and that an extension may be authorized.<sup>151</sup>

## C. Use

### 1. Access

It is widely shared that biomedical research is a public good. Therefore, the scientific community shall be able to access genetic materials and data that are stored in the various repositories. Large genetic databases are in fact important tool for a variety of biomedical researchers. Scientists’ access to biological samples and data is thus a crucial policy question. Several policies subscribe to the general view that knowledge arising out of the research should be accessible and that samples should be openly available to the scientific community.<sup>152</sup> Furthermore, the policies specify that access shall be balanced with the protection of the confidentiality of the participants in genetic research. Several guidelines also specify that sample sources shall be informed on whether third-parties have access to their samples or data at the time of consenting to participation in research, also providing that, ordinarily, the participant’s consent may allow broader forms of access.<sup>153</sup>

On discussing who may access samples and data, several guidelines simply state that access is admissible without further details. Few guidelines specify *who* is entitled to access: researchers,<sup>154</sup> the participant’s care provider,<sup>155</sup> or commercial companies.<sup>156</sup>

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<sup>149</sup> Isr. 2002, *supra* note 14, at 65.

<sup>150</sup> Godard et al., *supra* note 4, at S97.

<sup>151</sup> Brazil NHC 2005, *supra* note 52, at 3.

<sup>152</sup> CEST, *supra* note 38; NARC, *supra* note 38; ESHG 2002, *supra* note 60, sub 17; U.K. MRC, *supra* note 39; CIOMS, *supra* note 26; CCNE, *supra* note 50; HGC, *supra* note 13, at 5.25, 5.43.

<sup>153</sup> U.K. MRC, *supra* note 39; WHO 1997, *supra* note 10, at 13; NBAC, *supra* note 18; RMGA, *supra* note 17, at III sub 2; American Society of Human Genetics, *DNA banking and DNA analysis: points to consider. Ad Hoc Comm. on DNA Technology*, 42 AM. J. HUM. GENETICS 781-3 (1988) [hereinafter ASHG 1988]; HGC, *supra* note 13, at 3.69.

<sup>154</sup> CCNE, *supra* note 50; WHO 1997, *supra* note 10, at 13.

<sup>155</sup> Est. Act, *supra* note 35.

Sometimes, commercial companies, their employees and their contractors have to negotiate special conditions in order for them to access public collections.<sup>157</sup> Policies also differ in regulating *what* can be accessed. While a number of policies provide that third parties can access only anonymized or anonymous genetic data and/or medical records,<sup>158</sup> other guidelines provide that samples in general can be accessed.<sup>159</sup> Another issue relating to access is *for which purposes* access may be granted. The majority of guidelines addressing the issue provide that samples and/or data should be accessible for either research or commercial purposes. Only in Gambia, Estonia and Latvia, the participants' treating physicians can access genetic data that have been derived as part research on the collected sample.<sup>160</sup> The Estonia law also specifies that Estonia public research institutions may use the descriptions of DNA or parts thereof without charge.<sup>161</sup>

The policies that we are comparing do not discuss in detail the institutional arrangements and procedural *mechanisms* that should govern access to a genetic database. The policies tend not to engage in much analysis of the mechanisms governing investigators' access to a genetic database, arguably leaving up to the material transfer agreements and the data transfer agreements to specify the details of that relationship.<sup>162</sup> For instance, NARC explicitly provides that access is “[a]dmissible for both samples and data, but third parties shall be bound by contract protecting the sampled populations.”<sup>163</sup> On the other hand, the Council of Europe recommends that “[i]t should be the role of an independent body to oversee and regulate access to genetic databases.”<sup>164</sup> On similar lines, specific projects grant access to “academic, government and commercial researchers around the world who have protocols that are approved by relevant ethics committees and that are determined by the . . . Institutional Review Board to be consistent with the terms of the

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<sup>156</sup> U.K. MRC, *supra* note 39; Nuffield Council, *supra* note 38, at ¶ 5.43; HGC, *supra* note 13.

<sup>157</sup> Isr. 2002, *supra* note 14, at 50.

<sup>158</sup> UNESCO 2003, *supra* note 25; NARC, *supra* note 38; Est. Act, *supra* note 35; Japanese Guidelines, *supra* note 85; CDBI Exp. Rep., *supra* note 38; Isr. 2002, *supra* note 14, at 50, f.

<sup>159</sup> CEST, *supra* note 38; U.K. MRC, *supra* note 39; NARC, *supra* note 38; HUGO 1998, *supra* note 94; ASHG 1996, *supra* note 18 (requiring consent if identifiable); Lat. Law, *supra* note 68, at 17.2.

<sup>160</sup> Est. Act, *supra* note 35, at ¶ 16; Giorgio Sirugo et al., *A national DNA bank in The Gambia, West Africa, and genomic research in developing countries*, 26 NATURE REVIEW GENETICS 785-6(2004) (Guidelines of national DNA bank ¶ 15); Lat. Law, *supra* note 68, at 16.2 (“The doctor may receive such information without consent of the gene donor for the provision of emergency medical assistance”).

<sup>161</sup> Est. Act, *supra* note 35, at ¶ 16.

<sup>162</sup> HUGO 1996, *supra* note 28; Brazil NHC 2005, *supra* note 52, at 5.

<sup>163</sup> NARC, *supra* note 38.

<sup>164</sup> CDBI Exp. Rep., *supra* note 38, at recommendation 17.

informed consent documents.”<sup>165</sup> For large collections, the U.K. MRC recommends that “requests for access should usually be dealt with by a management committee, which should have an independent chair and some independent membership. Criteria for access should be agreed at the outset.”<sup>166</sup> In Sweden, “[t]he person responsible for the biobank considers applications regarding access to samples in the bank but may submit the application to the principal of the biobank for a determination.”<sup>167</sup>

Access to samples and mechanisms that govern access are also important in considering questions of *prioritization*.<sup>168</sup> Supplies of samples may be limited. To cope with the scarcity of the biological material, some policies suggest that the database prioritize access of third parties to exploit the collection at its best. Therefore, the U.K. MRC recommends that, “transparent arrangements for prioritizing requests for access are essential.”<sup>169</sup> Some guidelines also suggest that some selection based on the qualifications of the researcher is desirable. Thus WHO 1997 recommend that “[q]ualified researchers should have access if identifying characteristics are removed.”<sup>170</sup> As Godard et al. point out, “[a]t the national level, access to medical records or to samples for genetic research is normally restricted to qualified investigators and subject to institutional oversight, be it legislative or via ethics committees.”<sup>171</sup> The French National Ethics Committee also adds that “no discrimination shall take place among researchers belonging to the same category, which needs to be defined based on objectives standards (quality of researchers, participation to certain kinds of research projects).”<sup>172</sup> Sometimes, priority is given to the researchers building up the collections are entitled to exploit the stored samples with priority unless they are unable to use them in a way that will generate benefits for the participants, thus spoiling the promise made to the sample sources to use the samples in a productive way.<sup>173</sup>

Policies also discuss the *prerogatives* that third parties have in accessing samples and/or data. The policies often construe third party access as a potential burden in achieving the research goals that motivated the collection of the samples at the very beginning. Thus, policies provide that third party access “shall not disadvantage those involved in

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<sup>165</sup> The International HapMap Consortium, *supra* note 40, at 472.

<sup>166</sup> U.K. MRC, *supra* note 39, at 9.3.

<sup>167</sup> Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 1.

<sup>168</sup> *Id.* (recommending that access requests “are evaluated by a peer review process”).

<sup>169</sup> U.K. MRC, *supra* note 39, at 9.3.

<sup>170</sup> WHO 1997, *supra* note 10, at 13.

<sup>171</sup> Godard et al., *supra* note 4, at S96.

<sup>172</sup> CCNE, *supra* note 50, sub VI, 2.

<sup>173</sup> *Id.*; U.K. MRC, *supra* note 39, at 9.2 (“[i]n the case of collections made for a specific research project, it will usually be appropriate for the investigators making the collection to have priority access and the right to control use of the collection for the duration of the initial study”).

making/maintaining the collection.”<sup>174</sup> Furthermore, the European Society of Human Genetics explicitly provides that the “use or collection by third-parties shall not be allowed providing that there is not transfer of ownership.”<sup>175</sup> On similar lines, the U.K. MRC recommends that “[p]roper records of sample distribution must be kept and users must agree to return or destroy material surplus to their requirements and not use it for additional studies or pass it on to others.”<sup>176</sup> Some policies go further forbidding all transfers of samples.<sup>177</sup>

## 2. *Purpose of use*

We have previously discussed how biobanking activities challenge the traditional requirement to fully inform participants of all uses at the time consent is taken.<sup>178</sup> We will now discuss whether samples, genetic data, and health data can be used for other purposes beyond those for which consent was originally given, without first obtaining additional consent for the new uses. Different policy options have been suggested ranging from recommending collecting a broad consent at the time of the collection to requiring re-contacting participants whenever a new project is started.

### a) *Re-consenting and its alternatives*

Several guidelines recommend having an informed consent form that describes all known, future uses and *re-contacting participants* before each, unspecified research project is started.<sup>179</sup> The Canadian RMGA guidelines require re-contacting participants and seeking new informed consent for “other research than that specified in the original consent.”<sup>180</sup> However, if the samples are coded, “the participant should be able to choose whether or not to be recontacted in order to authorise the analysis of his DNA for other research.” The HapMap investigators have also chosen to re-contact donors of previously collected samples because the original consent “had not included discussions about sharing samples with other investigators, about samples being used for genetic variation

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<sup>174</sup> HGC, *supra* note 13, at 9.2; *see also*, U.K. MRC, *supra* note 39, at 9.2.

<sup>175</sup> ESHG 2002, *supra* note 60, sub 28.

<sup>176</sup> U.K. MRC, *supra* note 39, at 9.3.

<sup>177</sup> UNESCO 2003, *supra* note 25; Swed. Biobanks Act 2002, *supra* note 8, at art. 8 (“Tissue samples or parts of tissue samples stored in a biobank may not be transferred or handed out for commercial reasons”).

<sup>178</sup> *See supra*, II.A.1.a).

<sup>179</sup> Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 5; RMGA, *supra* note 17, at 8; Brazil NHC 2005, *supra* note 52, at 2.3; Brazil NHC 2004, *supra* note 22, at III.12.

<sup>180</sup> RMGA, *supra* note 17, at 8.

research that was not disease-specific or about the possibility that such research might raise group based concerns.”<sup>181</sup>

Some policies express criticism of re-consenting, and thus favor a less restrictive approach. The criticism is commonly based on grounds of invasion of privacy and practicability of scientific research, arguing that “repeated processes of re-consent for subsequent use are impractical and, moreover, may be considered as unnecessarily invasive,”<sup>182</sup> and/or that “the ability to re-contact a particular donor . . . would make impossible a number of scientifically useful analyses.”<sup>183</sup> Consequently, as alternatives to re-consenting, the policies propose several options: (1) a *general consent* in cases of “irreversible or reversible anonymisation of data and samples”, and re-consenting only if the samples are identified and if the research to be undertaken is of a “*fundamentally different nature*” from the one described in the original consent;<sup>184</sup> (2) a *broad consent* at the time of storage that encompasses all possible uses;<sup>185</sup> (3) uses other than those for which the samples were originally collected must be *authorized by a competent body*,

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<sup>181</sup> The International HapMap Consortium, *supra* note 40, at 470.

<sup>182</sup> HGC, *supra* note 13, at 94-95.

<sup>183</sup> NARC, *supra* note 38, at chapter 7.

<sup>184</sup> *Id.* See also, Isr. 2002, *supra* note 14, at 54, a (allowing future uses “restricted to similar type of research on genetic diseases (including psychiatric diseases)”). As a general rule, the Japanese guidelines require new consent for the use samples for a purpose different from that originally stated in the consent form. See, Japanese Guidelines, *supra* note 85, at rule 11, subrules 2-3.

<sup>185</sup> These guidelines are discussed *supra*, II.A.1.a).

which would then *waive* the requirement to seek re-consent;<sup>186</sup> and, finally, (4) *anonymizing* samples and data in an *unlinkable* fashion.<sup>187</sup>

b) *Samples stored for diagnostic purposes*

Human biological samples that are collected in occasion of diagnostic tests and in a clinical setting raise a parallel debate concerning what conditions apply for those samples to be used in biomedical research. The policies disagree on whether patients must specifically consent to their use in research. Some policies require that, in addition to consenting that samples are stored and used for diagnostic purposes, patients also *explicitly agree* that the same samples are used in biomedical research. Alternatively those patients must be offered a chance of opting out.<sup>188</sup> Other policies provide that the *informed consent requirement does not apply* if such samples are anonymized. Consequently, routine samples that are anonymized can be used in research without consent.<sup>189</sup> Sometimes policies combine these two last options by requiring informed

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<sup>186</sup> Ice. Act on Biobanks, *supra* note 11, at art. 9 (“[t]he board of the biobank may, if approved by the Data Protection Authority and the National Bioethics Committee, authorise the use of biological samples for other purposes than those for which the samples were originally collected, provided that important interests are at stake, and that the potential benefit outweighs any potential inconvenience to the donor of a biological sample or other parties”); Japanese Guidelines, *supra* note 85, at rule 11, subrules 2-3; NBAC, *supra* note 18, at 66-70 (referring to, and further specifying, the criteria set forth by federal rules waiving the consent requirement for research “of minimal risk at 45 CFR 46.116(d)”; Brazil NHC 2005, *supra* note 52, at 6.2.d (“in case of impossibility of the attainment of the specific consent”). In Sweden, the law waives the requirement for new consent if the consenting individual has deceased. In this case, “his or her next of kin shall be informed and after a reasonable time for consideration not opposed.” *See*, Swed. Biobanks Act 2002, *supra* note 8, at chapter 4, sect. 5.

<sup>187</sup> Japanese Guidelines, *supra* note 85, at rule 11, subrules 4-5; ACMG, *supra* note 115, at II, A; NBAC, *supra* note 18 (“if other appropriate protections were in place”).

<sup>188</sup> Denmark, *supra* note 94 (recommending that, if a patient “wishes that the relevant data should *not be allowed to be used* for research, any such wish must be complied with”).

<sup>189</sup> National Council for Science and Technology, *supra* note 34, at 14 (providing that “it is ethically acceptable to proceed without informed consent [for instance in studies involving] anonymous ‘left-over’ samples of blood, urine, saliva tissue specimens” and recommending that for epidemiological studies community consent must be collected if those studies involve “an entire community rather than [an] individual human subject”). In France, investigators may access samples and health information without consent for research purposes if the data are anonymized. Law No. 94-548 of July 1, 1994, J.O., July 2, 1994 (Fr.). *See also*, HUGO 1998, *supra* note 94 (recommending the use of routine samples obtained during medical care and stored without informing the patient of possible research uses provided the sample has been

consent whenever samples or data are not anonymized.<sup>190</sup> Finally, other policies recommend using a *generic consent* at the time the samples are collected.<sup>191</sup>

c) Retrospective studies with already collected samples

Similar issues are raised by *retrospective studies*, which involve the use of samples already collected without explicit informed consent for new research uses. In the past, samples have often been obtained without consent or without specific consent to their use in research projects other than those known at the time of collection. These collections are, however, often valuable. The World Medical Association stresses that retrospective epidemiological studies are important and that databases “are valuable sources of information for these secondary uses of health information.”<sup>192</sup> Several policies prevent using those samples unless *consent is obtained*.<sup>193</sup> Other policies recommend obtaining consent but also open the door for a *waiver*, commonly granted by an ethical review committee, whenever re-contacting the samples sources is impracticable.<sup>194</sup> Finally, the Royal College of Pathologists recommends using an *implied consent* model whereby research using archival tissues “should not proceed without first checking that each patient involved has not recorded an objection to such use.”<sup>195</sup> To be noted that most of

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anonymized prior to use). However several factors must be considered to allow the use of those samples, namely whether the samples “will be made anonymous; the degree to which the burden of contacting individuals may make it impracticable to conduct research, [the] existence and content of prior consent [and the] risks and benefits. ACMG, *supra* note 115, at II, A.

See also, Orr et al., *supra* note 5.

<sup>190</sup> UNESCO 2003, *supra* note 25, at art. 16; HGC, *supra* note 13, at 5.20; GNEC, *supra* note 8, at D.2.1.

<sup>191</sup> RCP, *supra* note 51, at recommendation 6 (recommending a generic consent “only if the work is ethically acceptable, if it is not in a controversial area and if it poses no risk of any adverse effect on the tissue donor”); U.K. MRC, *supra* note 39, at 9.3 (“allowing that patients are “made aware in any surgical consent form that they sign that surplus material may be used for research, and be given the opportunity to refuse”).

<sup>192</sup> World Med. Ass’n, *Declaration on Ethical Considerations Regarding Health Databases*, art. 5 (2000), at <http://www.wma.net/e/meetings/fulltext.htm>.

<sup>193</sup> Godard et al., *supra* note 4, at S90-91 (“many bodies have agreed that may be stored and used for other purposes than those originally intended if informed consent for banking and subsequent use has been obtained”).

<sup>194</sup> UNESCO 2003, *supra* note 25, at art. 17.a; ASHG 1996, *supra* note 18, at table 1. Japanese Guidelines, *supra* note 85, at rule 11, subrules 4-5 (providing that certain conditions must be fulfilled).

<sup>195</sup> RCP, *supra* note 51, at recommendation 10.

the policies compared as part of this study do not discuss whether already collected studies because they focus exclusively on *de novo* collection of human tissue.

### 3. *Benefit sharing*

The increasing private investment in genetic research and the potential profits that the applications of genetics research raise the issue of whether the benefits of genetic research ought to be shared with the participating individuals and communities. Since HUGO statement on benefit sharing,<sup>196</sup> commentators have increasingly argued that engaging in commercial human genetic research creates a special moral duty to share the benefits of that research with research participants or the group to which they belong. The link between commercialization and benefit sharing is discussed by the Nuffield Council:

So far discussion of property rights has concentrated on rights over the actual tissue that is removed. It is important to recall that a person may also claim an entitlement to share in any benefits arising from the exploitation of the tissue removed and, where relevant, any consequent intellectual property rights. Abandonment and donation, however, do not ordinarily give rise to intellectual property rights.<sup>197</sup>

Benefit sharing has also been established as a principle of international law in the area of biodiversity and genetic resources in food and agriculture. In fact, the Convention on Biological Diversity provides that “[e]ach Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis . . . to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties.”<sup>198</sup>

If a benefit may be defined as “a good that contributes to the well-being of an individual and/or a given community,”<sup>199</sup> there is little consensus and clarity on which benefits shall be shared and how benefit sharing would work practically.<sup>200</sup> Very few guidelines describe which benefits shall be shared and how benefit sharing would work practically. Furthermore, the policies differ widely on *what kind* of direct benefit shall be afforded to participant and *to whom*. Finally, to be noted that, although several guidelines put together problems of incentives with problems of benefit sharing, the two issues are

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<sup>196</sup> HUGO 2000, *supra* note 39.

<sup>197</sup> Nuffield Council, *supra* note 38, at ¶ 9.18.

<sup>198</sup> United Nations Environmental Programme, Convention on Biological Diversity, Dec. 29, 1993, art. 8j, 15(7), 19(2), 31 I.L.M. 818.

<sup>199</sup> HUGO 2000, *supra* note 39.

<sup>200</sup> *See*, THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH C.2 (Washington DC, Department of Health, Education and Welfare, 1979) (“[t]he term ‘benefit’ is used in the research context to refer to something of positive value related to health or welfare”).

conceptually separate. Traditionally, research subjects have participated in medical studies for idealistic reasons without receiving any economic benefit. However, providing a compensation for the discomfort of taking part into a genetic research project, as generally in all cases medical research, is distinguishable from the possibility the profits or other benefits of the research are shared with the participants as consequence of the growth of private investment and of commercial opportunities in genetic research. Discussing them together is problematic, and consequently we analyze them separately.<sup>201</sup>

a) What kind of benefits?

The benefits to be shared maybe conceptually distinguished in health-related vs. financial benefits, present vs. future benefits, and certain vs. contingent benefits. Translating benefit sharing into practical arrangements is often difficult, as discussed by the HapMap investigators:

Most of the benefits, however, will not be immediately apparent, and some might take years to materialize. So, in the short term, the main beneficiaries will not be sample donors, their families or their communities, but researchers, who will gain professional rewards and companies, that will be able to develop drugs, diagnostic tests or other commercial products from research using the HapMap.<sup>202</sup>

Several guidelines recommend sharing a variety of health-related benefits both present and future such as providing genetic counseling and screening,<sup>203</sup> giving access to new genetic tests, to medical information and to research findings, providing vaccines, tests, drugs, and treatments.<sup>204</sup> Other policies provide a variety of present, capacity building benefits such as contributing to health care infrastructure.<sup>205</sup>

Among the present benefits to the participating community, the HapMap investigators account the professional rewards to local investigators and companies, as well as “training in research ethics issues, including procedures to strengthen community

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<sup>201</sup> See *supra*, II.A.2.

<sup>202</sup> The International HapMap Consortium, *supra* note 40, at 473.

<sup>203</sup> Est. Act, *supra* note 35, at ¶ 11; CEST, *supra* note 38, at 50; Indian MRC, *supra* note 16, at 43.

<sup>204</sup> NARC, *supra* note 38; HUGO 2000, *supra* note 39; RMGA, *supra* note 17, at VI, 1; National Council for Science and Technology, *supra* note 34, at 16 (“any product developed through . . . research will be made reasonably available to the inhabitants of the community . . . or to the whole country”).

<sup>205</sup> HUGO 2000, *supra* note 39; National Council for Science and Technology, *supra* note 34, at 16 (“[c]onsideration should be given to the sponsoring agency agreeing to maintain health services and faculties established for purposes on the study in Kenya after the research has been completed”).

processes for obtaining informed consent.”<sup>206</sup> Participants from Nigeria were also each given “an equivalent of US \$8.00 and multivitamins worth – US \$4.00 to compensate them for their time and travel – a standard amount for participation in research involving blood draws in that part of Africa.”<sup>207</sup>

Concerning intellectual property rights, the guidelines that address the issue recommend that “intellectual property would be of the researcher with due consideration for benefit sharing”<sup>208</sup> and “not to pursue arrangements that allow the participant to receive the financial profit arising out of intellectual property rights.”<sup>209</sup> By contrast, other guidelines contemplate the possibility that participants “receive any profits from test sales” if genetic tests are commercialized.<sup>210</sup> A form of financial/contingent/future benefit is making a donation to humanitarian NGOs. Proposed by HUGO, the donation would operate “[i]n the case of profit-making endeavours [by donating] a percentage of the net profits (after taxes) to . . . local, national and international humanitarian efforts.”<sup>211</sup>

b) Direct vs. indirect benefits

The recipient of benefit sharing may be the community and/or individual participants. We refer to benefits that are primarily enjoyed at a community level as *indirect* benefits, and to benefits that are primarily enjoyed by individual participants as *direct* benefits.

The guidelines disagree on whether *indirect benefits* are sufficient or whether some form of direct benefit is required. When indirect benefits are permissible if not required, the policies disagree on how to define the “community” that participates in the benefit-sharing. In fact, the policies indicate different collective entities as beneficiaries of benefit-sharing: the community,<sup>212</sup> “the whole group that participated,”<sup>213</sup> the population,<sup>214</sup> the “general class of person to which [the participant] belongs,”<sup>215</sup> the

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<sup>206</sup> The International HapMap Consortium, *supra* note 40, at 473.

<sup>207</sup> *Id.*

<sup>208</sup> ESHG 2002, *supra* note 60, sub 27.

<sup>209</sup> CCNE, *supra* note 50, at 9.

<sup>210</sup> ACMG, *supra* note 115, at I, A, b.

<sup>211</sup> HUGO 2000, *supra* note 39; *see also*, RMGA *supra* note 17, at VI, 1.

<sup>212</sup> CEST, *supra* note 38; NARC, *supra* note 38 (“participating community”); RMGA, *supra* note 17; CIOMS, *supra* note 26, at guideline 10; WHO 1997, *supra* note 10, at 13; National Council for Science and Technology, *supra* note 34, at 16 (“to the inhabitants of the community in which research has been conducted”); Brazil NHC 2004, *supra* note 22, at III.15

<sup>213</sup> HUGO 2000, *supra* note 39.

<sup>214</sup> RMGA, *supra* note 17; CIOMS, *supra* note 26, at guideline 10.

<sup>215</sup> WHO 1997, *supra* note 10, at 13.

“host country” to which participants belong,<sup>216</sup> “the society as a whole and the international community”<sup>217</sup> or “all, with due regard to the dignity and human rights of each individual.”<sup>218</sup> A different form of indirect benefit-sharing is the “donation of a percentage of the net profits . . . to local, national and international humanitarian efforts.”<sup>219</sup>

A few guidelines provide that genetic research shall *never* provide direct benefits to the participants because there would be the risk of “coercing individuals to participate result in a form of undue coercion.”<sup>220</sup> By contrast, other guidelines are open to individual participant benefiting from participating in genetic research.<sup>221</sup>

Moreover, both direct and indirect benefits may be shared by the same research project. Thus, WHO 2003 recommends that “some kind of benefit will ultimately be returned, either to the individual from who the materials were taken, or to the general class of person to which that individual belongs.”<sup>222</sup> Addressing more generally biomedical research involving human subjects, the CIOMS guidelines give priority to direct benefits over indirect benefits, by recommending that “[r]isk to vulnerable subjects is most easily justified when it arises from interventions or procedures that hold out for them the prospect of direct health-related benefit. Risk that does not hold out such prospect must be justified by the anticipated benefit to the population of which the individual research subject is representative.”<sup>223</sup> This debate raises the interesting theoretical question of whether genetic research echoes the parallel controversy focusing on drug testing and the “just” benefit that participants in clinical trials are entitled to receive.

c) *Procedural aspects of benefit sharing*

A few guidelines provide some indication on how to construe a “community.” For instance, the HapMap project documents suggest that the “‘population’ refers to ‘a group of individuals who have a common geographical ancestry, a ‘community’ is a group with

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<sup>216</sup> Tri-Council, *supra* note 26, at 1.12; National Council for Science and Technology, *supra* note 34, at 16 (“ . . . to the whole country at the completion of successful testing”).

<sup>217</sup> UNESCO 2003, *supra* note 25, at art. 19.

<sup>218</sup> UNESCO 1997, *supra* note 53.

<sup>219</sup> HUGO 2000, *supra* note 39.

<sup>220</sup> NARC, *supra* note 38 (providing that “[t]o limit medical benefits to those who donate samples not only contravenes that principle, but also risks coercing individuals to participate. And it is unrealistic”); *see also*, National Council for Science and Technology, *supra* note 34, at 12.

<sup>221</sup> CIOMS, *supra* note 26, at guideline 5.

<sup>222</sup> WHO 2003, *supra* note 20, at recommendation 19.

<sup>223</sup> CIOMS, *supra* note 26, sub “General ethical Principle.”

a multitude of local units of social organization within a population.”<sup>224</sup> HUGO points out that there are “many different types of communities” and that the notion of community depends upon several dimensions, “including geography, race/ethnicity, religion or disease state.”<sup>225</sup> Although the guidelines provide little guidance, the many relevant communities are, to a certain extent, “self-defining [and] *community* is not an impossible hurdle in this context.”<sup>226</sup> However, defining the relevant “community” is an important step in benefit-sharing because a community engagement process is likely to be the best avenue to define the benefits that will be shared in any given research project. In other words, investigators and the community from which participants are to be drawn shall negotiate an appropriate benefit-sharing arrangement given the nature of the research, the nature of the risks involved for the community, and the benefits that are likely to originate from the research.

Fairness in negotiation is an important trait of the relationship investigators/community. In fact, “[t]he researcher should give no unjustifiable assurances about the benefits, risks or inconveniences of the research, for example, or induce a close relative or a community leader to influence a prospective subject’s decision.”<sup>227</sup> The procedural aspects of benefit-sharing are in the end still controversial, and further discussion and empirical evidence is needed to advance our understanding of the issue.

#### ***4. Feedback to participants, right to know, and right not to know***

The issue of whether and to what extent research participants shall be informed of research findings is problematic. Needless to say, the possibility of providing feedback applies only if the samples and/or data are linked to the identity of the sample source. A few guidelines make this consideration explicit, as in the case of the U.S. National Center for Human Genome Research statement, providing that “. . . there will be no possibility of returning information of clinical relevance to the donor or his/her family” because the sample are anonymous.<sup>228</sup>

##### ***a) Right to know and right not to know***

A number of policies provide that participant have a *right to know*.<sup>229</sup> Most prominently, the European Convention on Human Rights and Biomedicine provides that “[e]veryone is

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<sup>224</sup> The International HapMap Consortium, *supra* note 40, at 471.

<sup>225</sup> HUGO 2000, *supra* note 39.

<sup>226</sup> Graeme Laurie and Kathryn G. Hunter, *Benefit-sharing and public trust in genetic research*, BLOOD AND DATA – ETHICAL, LEGAL AND SOCIAL ASPECTS OF HUMAN GENETIC DATABASES 326 (Gardar Árnason et al eds., 2004).

<sup>227</sup> CIOMS, *supra* note 26, at guideline 6.

<sup>228</sup> NCHGR-DOE, *supra* note 99.

<sup>229</sup> See, e.g., UNESCO 2003, *supra* note 25, at art. 10 (“each individual has the right to decide “whether or not to be informed of the results of genetic examination and the

entitled to know any information collected about his or her health.”<sup>230</sup> On the other hand, several policies grant research participants *the right not to know*.<sup>231</sup>

The policies often require that “the information provided at the time of *consent* should indicate that the person concerned has the right to decide whether or not to be informed of the results.”<sup>232</sup> Several policies agree on this statement. CEST provides that “[t]he consent form shall mention whether a right to know/not to know exists and whether the participant decides or not to be informed.”<sup>233</sup> The Tri-Council policy statement recommends that, in taking consent, the issue “[of] whether results will be available from any analysis, and whether the subject wishes to receive results” shall be discussed.<sup>234</sup> Similarly, the Estonia Genome Project’s informed consent form grants participants both a right to know and a right not to know their genetic data.<sup>235</sup> In order to cope with the possibility that the genetic analysis unveils a false attribution of paternity, Estonian donors do not have a right to know their genealogies.<sup>236</sup>

Commonly in genetic research, investigators must inform the *ethics review committee* about the provisions concerning the feedback of results. Thus, the “[p]lans to inform subjects about the results of the study [are to] to be included in a protocol (or associated

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resulting consequences should be respected”); UNESCO 1997, *supra* note 53, at art. 5.c (“The right of every individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected”); Isr. 2002, *supra* note 14, at 69; ASHG 1996, *supra* note 18 (“[d]epending on the study, subjects may be given the opportunity to determine if they want to be informed of the results of their testing”); CEST, *supra* note 38, at 48; Lat. Law, *supra* note 68, at 4.2.4; Denmark, *supra* note 94, at 6.

<sup>230</sup> CHRB, *supra* note 53, at art. 10.

<sup>231</sup> Est. Act, *supra* note 35, at ¶ 11 (“[g]ene donors have the right not to know their genetic data”); U.K. MRC, *supra* note 39, at 4; WHO 2003, *supra* note 20, at recommendation 16 (“[a]dequate account must be taken of the privacy interest that individuals have in not knowing information about themselves”); WHO 1997, *supra* note 10, at table 7 “the wish of individuals and families not to know genetic information, including test results, should be respected, except in testing of newborn babies or children for treatable conditions”); Sirugo et al., *supra* note 160, at ¶ 12 (“research subjects have a right to know, but can decide that they do not want to know”); Brazil NHC 2004, *supra* note 22, at III.4. See, Roberto Andorno, *The right not to know: an autonomy based approach*, 30 J. OF MED. ETHICS 436 (2004).

<sup>232</sup> UNESCO 2003, *supra* note 25, at art. 10 (emphasis added).

<sup>233</sup> CEST, *supra* note 38, at 48.

<sup>234</sup> Tri-Council, *supra* note 26, at 8.7.

<sup>235</sup> Gene Donor Consent Form, Regulation No 125, Annex 1, 5-6 (Minister of Social Affairs, Estonia, 2001), at <http://www.geenivaramu.ee/index.php?lang=eng&sub=74>.

<sup>236</sup> *Id.*

documents) for biomedical research involving human subjects.”<sup>237</sup> Similarly, the U.K. MRC recommends the involvement of the ethics review committee in the decision about feedback: “[r]esearchers must decide at the beginning of a project what information about the results of laboratory tests done on samples should be available to the participants, and agree these plans with the Research Ethics Committee.”<sup>238</sup>

Rarely guidelines recommend putting “a mechanism in place for participants to change their minds,” thus, deciding not to be informed.<sup>239</sup> Interestingly, CEST guidelines recommend genetic counseling before consenting to a study in order to help the participant determine whether he/she wants to know possible results of the research or not.<sup>240</sup>

b) Limitations to right to know

Not all findings that genetic researchers produce have direct clinical implications for the health of the participants. Therefore, some guidelines favor the idea that feedback to individual participant must be limited to findings that are known to improve clinical management.<sup>241</sup> Sometimes individual feedback is construed as an exceptional event.<sup>242</sup> Moreover, even when clinical implications are present, disclosing research results “may not be appropriate.”<sup>243</sup> It is however unsettled whether the donors’ right not to know outweighs the obligation to disclose findings that are of immediate relevance for his/her health. This is true for Japan where there is no disclosure even though “the genetic

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<sup>237</sup> CIOMS, *supra* note 26, at appendix A.

<sup>238</sup> U.K. MRC, *supra* note 39, at 4.

<sup>239</sup> *Id.* at 8.4.

<sup>240</sup> CEST, *supra* note 38, at 48, at recommendation 8; *similarly*, Indian MRC, *supra* note 16, at 43.

<sup>241</sup> Isr. 2002, *supra* note 14, at 69; U.K. MRC, *supra* note 39, at 18-20 (limiting feedback to information that “have immediate clinical relevance [and] might impact on the donors’ interests”); RCP, *supra* note 51, at sub 67 (limiting feedback to information that could be life-saving citing as an example information on idiosyncratic drug reaction); Japanese Guidelines, *supra* note 85, at rule 9(1) (“[it] lacks significance in informing an individual donor of genetic information as such information is not accurate or certain enough to evaluate his/her state of health etc”).

<sup>242</sup> The NBAC recommends that:

... disclosure of research results to subjects represents an *exceptional circumstance*. Such disclosure should occur only when all of the following apply: a) the findings are scientifically valid and confirmed, b) the findings have significant implications for the subject’s health concerns, and c) a course of action to ameliorate or treat these concerns is readily available.

NBAC, *supra* note 18, at recommendation 14.

<sup>243</sup> U.K. MRC, *supra* note 39, at 19-20.

information has a serious impact on the life of the donor and his/her relatives.”<sup>244</sup> By contrary, in Latvia, the physician “may receive such information without consent of the gene donor for the provision of emergency medical assistance.”<sup>245</sup> This group of policies does not fully address – although it implicitly provides a negative answer – the questions of whether feedback could include information that might be relevant to reproductive choices, to planning one’s life course (investment planning, work and family activities), or to paternity. The guidelines also fail to distinguish between foreseeable results that were and “serendipity” results, i.e. results that were achieved by chance.

Other guidelines recommend that participants should only be informed about the *general results* of the research. This position lies on the view that a single research project does not generate irrefutable scientific facts.<sup>246</sup> Therefore, there should be a feedback on scientific progresses in general to satisfy the societal interest in accumulated research findings perhaps “through the use of newsletters,”<sup>247</sup> Similarly, HUGO statement on benefit points out that research participants “should . . . receive information about the general outcome(s) of research in understandable language,”<sup>248</sup> and that “[t]he ethical advisability of provision of information to individuals about their results should be determined separately for each specific project.”<sup>249</sup>

c) Whose obligation?

Whenever disclosure of individual results is appropriate, the central question is whether the investigators or the manager of the genetic database or repository have an obligation to inform participants directly or whether they have simply a duty to inform the treating physicians. On this issues, the U.K. MRC recommends a duty to disclose results that “have immediate clinical relevance” be imposed on researchers.<sup>250</sup> However, it leaves open the mechanism to implement such obligation, because it suggests that the duty is discharged by “ensur[ing that] the participant is informed.”<sup>251</sup> Other guidelines provide that participants shall be informed directly but that *genetic or medical counseling* should

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<sup>244</sup> Japanese Guidelines, *supra* note 85, at rule 9(2). But see,

<sup>245</sup> Lat. Law, *supra* note 68, at 16.2

<sup>246</sup> W. Grizzle et al., *Recommended Policies for Uses of Human Tissue in Research, Education, and Quality Control*, 123 ARCHIVES OF PATHOLOGY AND LABORATORY MED. 296–300 (1999) (the authors were all members of the Ad Hoc Comm. on Stored Tissue, College of American Pathologists).

<sup>247</sup> HGC, *supra* note 13, at 106.

<sup>248</sup> HUGO 2000, *supra* note 39.

<sup>249</sup> *Id.*

<sup>250</sup> U.K. MRC, *supra* note 39, at 18.

<sup>251</sup> *Id.*

be provided along with the disclosure of the information.<sup>252</sup> Finally, another view is that the obligation to feed results back to participants lies on a *health care professional* rather than on the investigators: “[t]he results of DNA analyses should be reported to the appropriate *health care professional*, who in turn has the responsibility of informing the patient or family of the results and their meaning.”<sup>253</sup> Moreover, “[a]ll genetic research studies involving identified or identifiable samples in which disclosure of results is planned should have medical geneticists and/or genetic counselors involved to ensure that the results are communicated to the subjects accurately and appropriately.”<sup>254</sup>

d) *Disclosure to family members and physicians*

Blood relatives and family members may be interested in having access to the samples and the genetic data that are stored in genetic database. In fact, those data may have a direct impact on their health. On the other hand, the interest of family members has to be balanced against the respect of the privacy of the research participant. An important policy dilemma arises out of this tension. Should genetic information be disclosed to family members without the participant’s consent? Not surprisingly, the policies disagree on whether relatives have a right to know research results. Some deny access to family members, some permit family members to access, some recommend access even if the participant is against its, and finally some do not take a side but discuss its controversial nature.<sup>255</sup>

A first group of policies that are aligned with CIOMS recommendations<sup>256</sup> do *not grant family members’ access* to the results of genetic tests. Thus, the legal frameworks of Estonia, Iceland, Sweden and the United Kingdom take an approach based on “individual

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<sup>252</sup> NBAC, *supra* note 18, at recommendation 16 (“appropriate medical advice or referral should be provided” along with the information”); Brazil NHC 2004, *supra* note 22, at III.5; RMGA, *supra* note 17, at IV, 3 (recommending that the availability of genetic counseling is considered “[i]n communicating results to the participant”).

<sup>253</sup> ASHG 1988, *supra* note 153 (emphasis added.)

<sup>254</sup> ASHG 1996, *supra* note 18.

<sup>255</sup> It is the case of the French recommendations, which emphasizes that “[g]iven the ‘communitarian’ trait of genetic information, it is necessary to reflect on the disclosure of the results to other family members who might be affected by the information . . . it is necessary to . . . further reflect on the issues . . . and possibly to debate it publicly.” *See*, CEST, *supra* note 38, at 48.

<sup>256</sup> CIOMS recommends that:

Investigators should not disclose results of diagnostic genetic tests to relatives of subjects without the subjects’ consent. In places where immediate family relatives would usually expect to be informed of such results, the research protocol . . . should indicate the precautions in place to prevent such disclosure of results without the subjects’ consent; such plans should be clearly explained during the process of obtaining informed consent.

CIOMS, *supra* note 26, at commentary on guideline 18

rights” and exclude the relatives’ right to know.<sup>257</sup> On the other hand, an Icelandic woman successfully challenged the transfer of her deceased father’s data into the Health Sector Database “as the data could indicate her father’s congenital characteristics and thus also possibly hers.” Consequently, it is to be noted that the Icelandic Supreme Court has given – albeit to a limited extent – appreciation to the interest of relatives in genetic information regarding a blood relative.<sup>258</sup>

Second, several guidelines *permit family members to access* stored genetic data because of the “serious impact on the life of the donor’s blood relatives.”<sup>259</sup> However access is often dependent only if certain conditions are met: an effective treatment is available, an ethics review committee has expressed its favorable opinion, that efforts to obtain consent from participant have been made, and that intention of relatives to know is clear.<sup>260</sup> The UNESCO International Declaration on Human Genetic Data provides that human genetic data “should not be disclosed or made accessible to . . . the family, except for an important public interest reason.”<sup>261</sup> What qualifies as “public interest” is unclear and the relatives’ right to know is not explicitly ruled out, thus leaving the question open for debate.

The consent of the sample source is not always required. While in general family members shall not be informed “without the explicit, written permission of the subject, except under extraordinary circumstances,”<sup>262</sup> a third, more liberal, view recommends that “[i]n certain situations, the principal researcher may disclose genetic information to the biological members of the family of the participant, *in spite of the refusal of the*

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<sup>257</sup> While in Estonia, relatives have no right to access genetic information or any other information that are stored in the database, the policies of Sweden and the United Kingdom are silent on the point *See*, Kaye et al., *supra* note 4, at 28.

<sup>258</sup> Supreme Court of Iceland, Judgment, No. 151/2003 (November 27, 2003), *available at* <<http://personuvernd.is/tolvunefnd.nsf/pages/60CD0F820FBD71D700256E4D004B1108>>.

<sup>259</sup> Japanese Guidelines, *supra* note 85, at rule 9(3).

<sup>260</sup> *Id.* *See also*, WHO 1997, *supra* note 10, at 13 (regarding the “control of DNA [as] familial, not individual” and recommending that “family members may request access to a sample to learn their own genetic status but not that of the donor”); U.K. MRC, *supra* note 39, at 25 (recommending that blood relatives are given an opportunity to learn about any research results that might impact on their interests”); HUGO 1998, *supra* note 94 (recommending to give “immediate relatives” access to stored DNA “[w]here there is a high risk of having or transmitting a serious disorder and prevention or treatment is available . . . for the purpose of learning their own status”).

<sup>261</sup> UNESCO 2003, *supra* note 25, at art. 10 and 14 (recognizing the right not to be informed, “where appropriate,” to the identified relatives who may be affected by the results).

<sup>262</sup> ASHG 1996, *supra* note 18.

latter.”<sup>263</sup> Disclosure is appropriate if the three following conditions are met: “a) non-disclosure could lead to serious and foreseeable harm to the biological family; b) the members of the biological family are identifiable; and, c) the risk of harm can be avoided through prevention or can be controlled through scientifically proven treatment.”<sup>264</sup>

In a few instances, policies distinguish the position of the spouse from the one of the other relatives.<sup>265</sup> When it comes to the participant’s spouse, WHO recommends a different regime: “[s]pouses should not have access to DNA banks without the donor’s consent, but may be informed that DNA has been banked.”<sup>266</sup> Reproductive freedom justifies an exception: “[i]f a couple is considering having children, it is the moral obligation of the party to provide the spouse with any relevant information.”<sup>267</sup>

Guidelines rarely provide that data can be shared with the participant’s *physician*. It is the case in at least two countries. In Gambia, “[d]ata concerning the genetic make-up of an individual, including susceptibility to certain diseases/conditions, will under no circumstances be provided to anyone apart from the individual or their doctor on request.”<sup>268</sup> Similarly, in Estonia, data may be disclosed to the “the doctor of the gene donor.”<sup>269</sup> Moreover, some of the policies granting access to blood relatives recommend *involving the treating physician* in the process “to discuss with his patient the issue of follow-up with the family and the consequences of refusing to transmit the information in question.”<sup>270</sup>

### III. Emerging consensus and unresolved controversies

The comparative analysis of the policies that we have included in the study shows the contradictory or inconclusive nature of the existing guidelines. However, the analysis also shows that there is some policy consensus, albeit on a limited number of issues.

Most policies require that a written, informed consent must be collected, at least once in the process, for samples and data to be collected and stored in a genetic database. It is

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<sup>263</sup> RMGA, *supra* note 17 (emphasis added.)

<sup>264</sup> *Id.*

<sup>265</sup> *Id.* (“[n]o genetic information should be transmitted by the principal researcher to the spouse without the express consent of the participant”).

<sup>266</sup> WHO 1997, *supra* note 10, at 13.

<sup>267</sup> *Id.*

<sup>268</sup> Sirugo et al., *supra* note 160, at ¶ 15.

<sup>269</sup> Est. Act, *supra* note 35, at ¶ 20.

<sup>270</sup> RMGA, *supra* note 17 (emphasis added). ASHG recommends that “[t]he results of DNA analyses should be reported to the appropriate health care professional, which in turn has the responsibility of informing the . . . family of the results and their meaning.” See, ASHG 1988, *supra* note 153.

also widely acknowledged that using already collected samples and data is acceptable if it is impossible to re-new the already taken informed consent, or obtain a new informed consent, from the sample source. Most of the guidelines also provide that the financial incentives offered to research participants must never be excessive, i.e. constituting undue influence to participate in genetic research. However, the determination of whether information that is provided to research participants at the time of the sample collection is adequate and whether using samples and/or data for further research that had not been specified at the time of consent is permissible remains a matter of controversy. Whether consent of the individual needs to be complemented by consent of others concerned, such as the family or community is also undetermined. Moreover, it is controversial whether samples taken during clinical or research activities should require informed consent in order to allow inclusion in genetic databases and whether irreversibly anonymized tissue can be used in genetic research without informed consent.

The majority of guidelines also recognize research participants' right to withdraw their consent. However, several issues remain controversial – what is the best mechanism to implement the exercise of participants' right of withdrawal – or inconclusive – whether it affects both samples and data and the timing of the exercise of the right of withdrawal, especially in relation to ongoing studies.

Regarding the conditions of storage and use of samples, most of the guidelines require some form of anonymization of data and samples to protect the privacy of the research participants. A few guidelines and projects, the HapMap among them, choose the complete anonymization of the samples at the time of the samples collection. However, even if anonymization is commonly favored, several issues remain unresolved, namely what must be protected as confidential, what is the best arrangement to ensure that confidentiality is maintained, and who should decide on that. Moreover, the comparison of guidelines is complicated by the fact that the policies use different and at times unclear definitions of the various mechanisms of anonymization of data and samples.

Another major area of controversy deals with the rules of ownership and commercialization. Regarding commercialization, it is unresolved whether ownership of samples shall be assigned to the biobank or shall rest with the research participants, or even more radically, whether ownership of samples shall be prohibited *tout court* since genetic resources may be considered as “the heritage of humanity.”<sup>271</sup> On the other hand, the policies agree on the fact that the entity responsible for the collection must ensure that the integrity of the sample is protected and that it is used in an appropriate manner. Furthermore, commercialization raises contrasting policy statements, ranging from the prohibition of sharing samples with commercial companies to policies acknowledging the potential commercial uses of samples and genetic data. The role of the legal protection of intellectual property is also controversial. At one extreme a patenting regime that grants patents on gene sequences seems inconsistent with the view that genetic resources are

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<sup>271</sup> UNESCO 1997, *supra* note 53, at art. 1.

“the heritage of humanity;”<sup>272</sup> on the other hand, many policies recognize intellectual property protection as needed to make commercialization of human genetic research viable, and as the best mechanism for participant to claim “an entitlement to share in any benefits arising from the exploitation of the tissue removed.”<sup>273</sup>

The policies compared in this paper also present conflicting and inconclusive positions on benefit sharing, and in particular disagreement on what kinds of benefits should be shared, with whom those benefits should be shared, and the mechanisms of negotiation of the benefit sharing agreement.

Finally, the policies express more agreement on the issue of feedback to participants. Many policies grant research participants a right to know, a right not to know, or both of them. On the other hand, the policies are inconclusive on issues such as whether genetic counseling shall be provided along with feedback, what kinds of information shall be communicated to research participants, and on whether the investigators or the biobankers are responsible for communicating the results directly to the research participants rather than to their treating physicians. Finally, the policies disagree on whether relatives have a right to know research results.

#### **IV. Conclusions**

Human genetic databases raise highly complex ethical issues in health policy, especially whenever biological samples are stored and used in combination with information on individuals’ health, lifestyle or genealogy. In this paper, we have compared a set of policies – national laws, international and national guidelines, and policy statements by professional organizations – addressing human genetic databases looking at whether the existing regulatory instruments provide sufficient policy guidance. Unfortunately, the comparative analysis of the policies that we have included in the study shows the contradictory or inconclusive nature of the existing guidelines, policy consensus being reached only on a limited number of issues. Further discussions in the literature and other forums, as well as empirical research, is therefore required.

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<sup>272</sup> See, e.g., The Wellcome Trust ,Summary of Principles Agreed at the First International Strategy Meeting on Human Genome Sequencing (1996), at <http://www.gene.ucl.ac.uk/hugo/bermuda.htm> (recommending that primary genomic sequences should be, and rapidly released, in the public domain); Declaración de Manzanillo, *supra* note 5, at sixth, b (pointing out the “need to limit . . . the availability of patents to the strict limits of the scientific contribution, avoiding unjustified extensions that would be an obstacle to future investigations, also excluding the possibility to patent genetic material in itself”).

<sup>273</sup> Nuffield Council, *supra* note 38, at ¶ 9.18.

# Appendix 1

## I. Guidelines on biobanks and medical records

1. ASHG 1987 – American Society of Human Genetics: Ad Hoc Committee on DNA Technology. Report on DNA banking and DNA analysis: Points to Consider (1987)
2. Brazil NCH – National Health Committee, Resolution 347/05: Projects with Use or Storage of Biological Materials (13 January 2005)
3. CCNE – Comité Consultatif National d'Éthique: Avis et rapport No. 77 (France, 2003)
4. CEST – Commission de l'éthique de la science et de la technologie: Les enjeux éthiques des banques d'information génétique : pour un encadrement démocratique et responsable (2003)
5. Denmark – Danish Research Agency (Forskningstyrelsen), Health Science Information Banks - Biobank (1996)
6. ESHG European Society of Human Genetics: Data storage and DNA banking: Technical, Social and Ethical Issues (2002)
7. Estonia – Human Genes Research Act (2000)
8. European ECVAM – S. Orr et al., “The establishment of a network of European human research tissue banks,” ATLA 29, 125-134 (2001)
9. Gambia – Guidelines of national DNA bank (2004)
10. HUGO 2002 – HUGO Ethics Committee: Statement on Human Genomic Databases (2002)
11. Iceland – Act on Biobanks 100/2000; Act of Patient's Rights; Act on a Health Sector Database, No. 139 (1998)
12. The Israel Academy Committee for Bioethics, Population-based large-scale Collections of DNA samples and Databases of Genetic Information (2002)
13. Latvia – Human Genome Research Law (Adopted by Latvian Parliament Saeima on June 13, 2002 and proclaimed by President of Latvia on July 3, 2002)
14. Swedish Law – Biobanks [Health Care] Act 2002, no. 297 (2002)
15. UNESCO 2003 – United Nations Educational, Scientific and Cultural Organization: International declaration of human genetic data (2003)
16. WHO 2003 – European Partnership on Patients Rights and Citizens Empowerment (A network of the World Health Organization Regional Office for Europe): Genetic databases. Assessing the benefits and the impact on human & patient rights. Report for Consultation to the . Geneva, WHO World Health

- Organization: Genetic Databases: Assessing the benefits and the impact on human & patient rights (2003)
17. WHO 1998 – World Health Organization: Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services (1997)

## **II. Guidelines addressing human tissue**

18. ACMG – American College of Medical Genetics: Statement on Storage and Use of Genetic Materials (1995)
19. CDBI 2002 – Council of Europe Steering Committee on bioethics: Proposal for an instrument on the use of archived human materials in biomedical research (2002)
20. CDBI 2002 expl. Rep. – Council of Europe Steering Committee on bioethics: Explanatory Report (2002)
21. HUGO 1998 – Statement on DNA Sampling: Control and Access (1998)
22. Japan – Ethics Guidelines for Human Genome/Gene Analysis Research (2001)
23. NARC – North American Regional Committee: Model Ethical Protocol for Collecting DNA Sample (1997)
24. NBAC – U.S. National Bioethics Advisory Commission: Research Involving Human Biological Materials: Ethical Issues and Policy Guidance (1999)
25. Nuffield Council: Human Tissue Ethical and Legal Issues (1995)
26. RCP 2001 – Royal College of Pathologists: Transitional guidelines to facilitate changes in procedures for handling “surplus” and archival material from human biological samples (2001)
27. U.K. MRC – U.K. Medical Research Council: Human Tissue and Biological Samples for use in Research - Operational and Ethical guidelines (2001)