



## **Ethics assessment in different fields**

### **Biobanking**

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**Annex 2.c.4**  
**Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices  
and Institutions in the EU and selected other countries**  
*Deliverable 1.1*

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## 1 Introduction

Biobanks collect biological samples and associated data for medical-scientific research and diagnostic purposes and organise these in a systematic manner for use by others.<sup>1</sup> The systematic collection of human cells and tissue samples has a long history in the service of medicine.<sup>2</sup> In the past, such biorepositories resided largely in the seclusion of pathology institutes.<sup>3</sup> In recent times, large patient registries and population surveys have been established to enable the linking of biological and genetic data with general patient data.<sup>4</sup> Several factors have contributed to the move from small, biological repositories to large-population-based collections, including technical and computational advances (e.g., high-throughput genomics techniques), new systematic approaches and the growing level of exchange of information and biological material between researchers.<sup>5</sup> Large-scale biobanks allow for the exploration of the genetic basis of common multifactorial disease<sup>6</sup> and the contribution of gene-environment interactions to disease.<sup>7</sup> Discovery of disease-triggering effects critically depends on the study of large collections of biological material including tissues, blood or other body fluids from a large number of patients and healthy individuals, annotated with well-documented and up-to-date information on the sample donor including the clinical course of the disease.<sup>8</sup> Insight into the function and medical relevance of human genes and their products, in addition to the biological networks in which they function is also a prerequisite for the development of more effective drugs for specific patient groups in the context of personalised medicine.<sup>9</sup> Over the last decade and a half, a number of biobanks have been established in several countries, including the Icelandic Health Sector Database, the Estonian Genome Project, UK Biobank, Generation Scotland and the CARTaGENE project in Quebec.<sup>10</sup>

The aim of these population-based biobanks is to discover biomarkers for disease susceptibility within a specific population through prospective molecular epidemiology.<sup>11</sup> Population-based biobanks represent only one type of biobank, however. In contrast, disease-oriented biobanks, which may include tissue, isolated cells, blood or other body fluids and specimens are collected from an individual in the context of clinical care.<sup>12</sup> The case-control study is a specific format of disease-oriented biobanks which contains about equal numbers of samples and data from diseased and healthy individuals.<sup>13</sup> Another specific format is the

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<sup>1</sup> Gottweis, Herbert, Jane Kaye et al., “Biobanks for Europe: A challenge for governance: A Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research”, Brussels, European Commission, 2012, p. 8.

<sup>2</sup> Hoeyer, Klaus Lindgaard, “Size matters: the ethical, legal and social issues surrounding large-scale genetic biobank initiatives”, *Norsk Epidemiologi*, Vol. 21, No. 2, 2012, pp. 211-220 [p. 211].

<sup>3</sup> Gottweis et al., op. cit., 2012, p.8.

<sup>4</sup> Gottweis, Herbert and K. Zatloukal, “Biobank governance: trends and perspectives”, *Pathobiology*, Vol. 74, 2007, pp.206-211 [p. 208].

<sup>5</sup> Cambon - Thomsen, Anne, “The social and ethical issues of post-genomic human biobanks”, *Nature Reviews Genetics*, Vol. 5, November 2004, pp. 866-873 [p. 867].

<sup>6</sup> Biomedical research has progressed from studying rare monogenic diseases to common multifactorial diseases.

<sup>7</sup> Cambon - Thomsen, op. cit., 2004, p. 867.

<sup>8</sup> Asslauer, Martin and Kurt Zatloukal, “Biobanks: transnational, European and global networks”, *Briefings in Functional Genomics and Proteomics*, Vol. 6, No. 3, 2007, pp. 193-201 [p.193].

<sup>9</sup> Ibid.

<sup>10</sup> Otlowski, Margaret, Dianne Nicol and Mark Stranger, “*Biobanks Information Paper 2010*”, 2010, [http://www.nhmrc.gov.au/\\_files\\_nhmrc/file/your\\_health/egenetics/practioners/biobanks\\_information\\_paper.pdf](http://www.nhmrc.gov.au/_files_nhmrc/file/your_health/egenetics/practioners/biobanks_information_paper.pdf)

<sup>11</sup> Gottweis et al., op. cit., p. 15.

<sup>12</sup> Asslauer and Zatloukal, op. cit., 2007, p.195.

<sup>13</sup> Ibid.

tissue bank which contains diverse collections of tissue specimens annotated with detailed information regarding the existing diseases, and in some cases, information on response to therapy as well as final disease outcome.<sup>14</sup> Biobanking also takes place in parallel with clinical trials performed by various clinical research organisations and/or investigator-driven clinical trials in Europe and elsewhere.<sup>15</sup> Other specific biobanking formats include Guthrie cards<sup>16</sup>, cord blood biobanks<sup>17</sup> and stem cell biobanks.<sup>18</sup>

As a huge number of biological and medical parameters (e.g., type of disease, treatment, genetic polymorphisms, accompanying disease, lifestyle, etc.) influence and characterise the disease of individual patients and split classical diseases into several new sub-entities, several hundreds or thousands of samples have to be investigated in order to cope with such biological/medical diversity.<sup>19</sup> Therefore the integration (or pooling) of data across biobanks is essential in order to obtain the large number of participants and samples necessary to carry out research investigating, for example, the interplay between genetic, lifestyle, environmental and social factors that determine health and (complex) diseases.<sup>20</sup> The vision within Europe is to link biobanks together as part of a pan-European infrastructure in order to support medical research and health care.<sup>21</sup> The preparatory phase for networking biobanks in Europe has taken place through the Biobanking and Biomolecular Infrastructure (BBMRI).<sup>22</sup>

The trend towards larger biobanks raises concerns about how to ensure the ethical use of human samples and the associated information<sup>23</sup>, in addition to more general socio-political issues, such as the perception and the acceptance of biobanks in society.<sup>24</sup> Indeed biobanks have received considerable attention in the ELSI (ethical, legal and social issues) literature in recent years.<sup>25</sup> This attention has come about because biobank-related research challenges the traditional normative framework for biomedical research and its well-known components.<sup>26</sup> Research in the area of ethics of biobanking has focused on issues including privacy, informed consent, ownership of samples and information, benefit sharing and governance.<sup>27</sup> Before discussing these issues, we look first at the values and principles that inform ethical discussion in the area of biobanking.

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<sup>14</sup> Ibid

<sup>15</sup> Gottweis et al., op. cit., p. 16.

<sup>16</sup> A Guthrie card or a blood spot card is a special specimen collection paper for collecting and holding spots of blood during routine nationwide neonatal screening programmes.

<sup>17</sup> <http://www.nhsbt.nhs.uk/cordblood/about/>

<sup>18</sup> Gottweis et al., op. cit., p. 16.

<sup>19</sup> Asslaber and Zatloukal, op. cit., 2007, p.197.

<sup>20</sup> Gottweis et al., op. cit., 2012, p. 19.

<sup>21</sup> Ibid.

<sup>22</sup> Ibid, p. 54.

<sup>23</sup> Cambon - Thomsen, op. cit., 2004, p. 867.

<sup>24</sup> Gottweis et al., op. cit., p. 23.

<sup>25</sup> Hawkins, Alice, K. and Kieran C. O'Doherty, "Who owns your poop?": insight regarding the intersection of human microbiome research and the ELSI aspects of biobanking and related studies", *BMC Medical Genomics*, Vol. 4, No. 72, 2011.

<sup>26</sup> Lunshof, Jeantine, E., Ruth Chadwick, Daniel B. Vorhaus and George M. Church, "From genetic privacy to open consent", *Nature Genetics Reviews*, Vol. 9 (May 2008), pp. 406-411 [p. 406].

<sup>27</sup> Hawkins et al., op. cit., 2011.

## 2 Values and principles

The general principles of autonomy, beneficence/non-maleficence and justice, generally translated into actions through informed consent, protection of confidentiality and privacy and non-discrimination measures<sup>28</sup> frequently appear in the literature on ethics of biobanking. Large-scale biobanking has had to adapt the ethical frameworks that were developed for smaller biobanks, while keeping the ethical principles themselves.<sup>29</sup> Due to the flood of information enabled by biobanking and related technologies, established concepts of research ethics have been “stretched to their limits” and issues of consent for research, privacy and confidentiality are being re-examined.<sup>30</sup> The translation of informed consent into practice faces difficulties in the case of large-scale biobanks, long-term use of samples or data, or numerous exchanges.<sup>31</sup> For example, although the donation of blood or tissue samples for a specific research project or collection does not at first glance pose any significant problems to acquiring obtained consent, the development of large biobanks and the many potential utilisations of biological samples raise the difficult question of how to obtain consent for a multitude of possible research purposes.<sup>32</sup> Potential research participants cannot be informed of the potential risks and benefits of the research as the biobank – or biobankers – do not know what these will be.<sup>33</sup> The Nuremburg Code and Declaration of Helsinki “envisioned a specific, discrete research project, not a tool for use on unforeseen and unforeseeable research projects”.<sup>34</sup> Some policies for the use of biobanks – such as a presumed consent to all possible future uses of samples and/or data - constrain the right of individuals to decide on whether and the manner in which their body and related data will be used in research.<sup>35</sup> Increasingly, solidarity and reciprocity - rather than autonomy - have emerged as ethical principles guiding informed consent.<sup>36</sup>

Developments in large-scale biobanking highlight the fact that the guarantee of absolute privacy and confidentiality is not a promise that medical and scientific researchers can deliver.<sup>37</sup> This situation has rendered data protection, confidentiality and privacy key concerns in the context of biobanking in the 21<sup>st</sup> century.<sup>38</sup> Given that the potential of a biobank lies in the linking of biological samples to clinical and personal data, anonymisation is the least preferred option for the identification of biological samples.<sup>39</sup> This has implications not only for confidentiality but also for privacy.<sup>40</sup> The protection of information is one of the most

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<sup>28</sup> Cambon -Thomsen, op. cit., 2004, p. 867.

<sup>29</sup> Ibid, p. 867.

<sup>30</sup> Lunshof et al., op. cit., 2008, p. 406

<sup>31</sup> Cambon, op. cit., 2004, p. 869.

<sup>32</sup> Gottweis and Zatloukal, op. cit., 2007, p. 209.

<sup>33</sup> Greely, Henry, T. “The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks”, *Annu. Rev. Genomics Hum. Genet.*, Vol. 8, 2007, pp. 343-364 [p.357].

<sup>34</sup> Ibid, p. 357.

<sup>35</sup> Ibid, p. 869.

<sup>36</sup> Chadwick, Ruth and Kare Berg, “Solidarity and equity: new ethical frameworks for genetic databases”, *Nature Reviews Genetics*, Vol. 2, April 2001, pp. 318-321 [p. 406].

<sup>37</sup> Lunshof et al., op. cit., 2008, p. 406.

<sup>38</sup> Nuffield Council on Bioethics, *Solidarity: reflections on an emerging concept in bioethics*, Nuffield Council on Bioethics, 2011.

<sup>39</sup> Fullerton, Stephanie, M., Nicholas R. Anderson, Greg Guzauskas, Dena Freeman and Kelly Fryer-Edwards, “Meeting the Governance Challenges of Next-Generation Biorepository Research”, *Science Translational Medicine*, Vol. 2, No. 15, 2010, pp. 1-4 [p.1]

<sup>40</sup> Nuffield Council on Bioethics, op. cit., 2011.

sensitive issues in biobanking, with the issue of the measures taken by biobanks to prevent possible misuse of data by employers and insurers being particularly salient.<sup>41</sup>

### 3 Ethical issues

#### 3.1 OWNERSHIP

Debate has been ongoing as to whether a biological specimen, such as a tissue, a tumour or blood in some respect ‘belongs’ to the individual it came from, at least for a defined period of time.<sup>42</sup> These debates are informed by case law including the much-discussed judgement of the Supreme Court of California in *John Moore v. Regents of the University of California*.<sup>43</sup> This was a seminal case concerning a patient’s interest in the profits derived from patents on a cell line generated from his spleen tissue.<sup>44</sup> The court’s decision to deny his action was based on the reasoning that tissue in itself could not be considered property.<sup>45</sup> The tissue could only become property on being turned into a cell line and after having been invested by human labour.<sup>46</sup> The Moore case has become a touchstone for commentaries on the ethical and legal issues associated with the use of human tissue and is a frequent reference point for regulatory, advisory and ethics bodies.<sup>47</sup> Similarly, the case of Henrietta Lacks,<sup>48</sup> an African American woman whose cervical cancer cells were used in medical research in order to create profitable immortal cell lines without her knowledge or consent highlights the importance of policy attention to ownership and control of biological specimens, in addition to obligations to third party relatives in third party research.<sup>49</sup> Caulfield and McGuire report that reaction to the 2013 publication of the genome sequence of a HeLa cell line and its data “implied a baseline expectation regarding the procurement of consent from biological relatives prior to releasing genome sequence data”.<sup>50</sup> However, the law relating to ownership and control of human biological material varies in different countries and remains unclear in some countries.<sup>51</sup> Moreover, individuals may still retain a degree of control over biological materials, primarily in the form of the right to withdraw or to request destruction of the sample.<sup>52</sup>

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<sup>41</sup> Ibid.

<sup>42</sup> Hawkins et al., op. cit., 2011.

<sup>43</sup> Tutton, R., “Biobanking: Social, Political and Ethical Aspects”, *Encyclopaedia of Life Sciences*, John Wiley & Sons, Ltd, Chichester, 2010, DOI: 10.1002/9780470015902.a0022083

<sup>44</sup> Charo, R. Alta, “Body of Research – Ownership and Use of Human Tissue”, *The New England Journal of Medicine*, Vol. 355, No. 15, 2006, pp. 1517-1519 [p.1517].

<sup>45</sup> Tutton, op. cit., 2010.

<sup>46</sup> Ibid.

<sup>47</sup> Ibid.

<sup>48</sup> Skloot, Rebecca, *The Immortal Life of Henrietta Lacks*, New York, Crown, 2010.

<sup>49</sup> Caulfield, T. and Amy L. McGuire, “Policy Uncertainty, Sequencing, and Cell Lines”, *G3*, Vol. 3, 2013, pp. 1205-1207, [p.1205].

<sup>50</sup> Ibid, p. 1205.

<sup>51</sup> Caulfield, Timothy, Sarah Burningham, Yann Joly, Zubin Master, Mahsa Shabani, Pascal Borry, Allan Becker, Michael Burgess, Kathryn Calder, Christine Critchley, Kelly Edwards, Stephanie M. Fullerton, Herbert Gottweis, Robyn Hyde-Lay, Judy Illes, Rosario Isasi, Kazuto Kato, Jane Kaye, Bartha Knoppers, John Lynch, Amy McGuire, Eric Meslin, Dianne Nicol, Kieran O’Doherty, Ubaka Ogbogu, Margaret Otloswski, Daryl Pullman, Nola Ries, Chris Scott, Malcolm Sears, Helen Wallace and Ma’n Zawati, “A review of the key issues associated with the commercialization of biobanks”, *Journal of Law and the Biosciences*, 2014, pp. 94-110, [p.105]

<sup>52</sup> Caulfield and McGuire, op. cit., 2013.

Large-scale population biobanks try to clarify this issue by informing participants that they are not entitled to ownership of samples or information held by the biobank.<sup>53</sup> For example, in its Ethics and Governance Framework, the UK Biobank states that it is the legal owner of the database and the sample collections which conveys certain rights such as the right to take legal action against unauthorised use or abuse of the database or samples, in addition to the right to sell or destroy the samples. However, the framework goes on to state that the UK Biobank “does not intend to exercise all of these rights; for example, it will not sell samples” (p. 12).

### 3.2 INFORMED CONSENT

The fundamental principle underpinning the governance framework for medical research is that individual research participants must be respected. One way in which this is demonstrated is through the process of obtaining informed consent from research participants prior to the commencement of the research. While informed consent does not in itself protect an individual, it allows individuals to exercise their fundamental rights to decide whether and how their body, its parts, and the associated data will be used in research.<sup>54</sup> Biobanks raise particular concern with regard to informed consent; the crux of the concern relates to the ability of a potential research participant to give truly informed consent for a research project in which potential outcomes and effects are unknown and it is not possible to stipulate all of the research uses of samples and data contained in the biobank at the time that participants are recruited.<sup>55</sup> Broad consent has emerged as a practical solution to this problem and is now the norm for biobank recruitment.<sup>56</sup> Participants are asked to consent to the use of samples and data within a biobank at the time of collection rather than to a specific project or types of research as specified in traditional formulations of informed consent.<sup>57</sup> The use of broad consent has led to heated debate as to whether it is ethically appropriate, however. In an influential article, Hansson et al. argue that broad consent and consent for future research are valid ethically and should be recommended for biobank research on the following conditions: personal information is handled safely, donors of biological samples are granted the right to withdraw consent; and new research studies or changes to the legal or ethical authority of a biobank are approved by an ethics review board.<sup>58</sup> Hofmann offers a number of arguments against this position.<sup>59</sup> First the issue of safe handling of information is precisely the key issue in biobank research; this issue “has to be addressed and not evaded by criteria of little practical relevance”.<sup>60</sup> Second, there are practical challenges to withdrawal such as the distribution of biological materials and data from analysis over many locations beyond the control of the individual researcher. Third, review boards are often not able to assess the information safety of research participants and, in many cases, may not be competent to review biobank research. Many European guidelines take the view that broad consent is

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<sup>53</sup> Otlowski, Margaret, Dianne Nicol and Mark Stranger, “*Biobanks Information Paper 2010*”, [http://www.nhmrc.gov.au/\\_files\\_nhmrc/file/your\\_health/egenetics/practioners/biobanks\\_information\\_paper.pdf](http://www.nhmrc.gov.au/_files_nhmrc/file/your_health/egenetics/practioners/biobanks_information_paper.pdf)

<sup>54</sup> Cambon - Thomsen, op. cit., 2004, p. 869.

<sup>55</sup> Hawkins et al., op. cit., 2011; Gottweis et al., op. cit., 2012, p. 51.

<sup>56</sup> Ibid.

<sup>57</sup> Ibid.

<sup>58</sup> Hansson, Mats, G., Joakim Dillner, Claus R. Bartram, Joyce A. Carlson, and Gert Helgesson, “Should donors be allowed to give broad consent to future biobank research?”, *The Lancet Oncology*, Vol. 7, March 2006, pp. 266-269 [p. 266].

<sup>59</sup> Hofmann, B. “Broadening consent – and diluting ethics?”, *J Med. Ethics*, Vol. 35, 2009, pp. 125-129.

<sup>60</sup> Ibid, p. 126.



acceptable for “unspecified future research use” of samples.<sup>61</sup> Some Asian countries have a similar approach, with Japanese guidelines, for example, containing the idea of “comprehensive consent”.<sup>62</sup> The United States, by comparison, tends to prefer a tiered or multi-layered consent in which participants are asked to make different choices on a detailed form.<sup>63</sup> The Personal Genome Project<sup>64</sup> at Harvard Medical School has proposed a different approach through the mechanism of ‘open consent’. In open consent, volunteers consent to unrestricted re-disclosure of data originating from a confidential relationship, namely their health records, and to unrestricted disclosure of information that emerges from any future research on their genotype-phenotype data set, the information content of which cannot be predicted.<sup>65</sup> The open consent model assumes that conventional assurances of anonymity, privacy or confidentiality cannot be given.<sup>66</sup> While privacy and confidentiality can be protected, they cannot and should not be guaranteed to participants.<sup>67</sup> The leading moral principle is veracity - telling the truth – which is viewed as a necessary prerequisite for the exertion of substantive autonomy.<sup>68</sup>

### 3.3 PROTECTING PRIVACY AND DATA PROTECTION

The major risk of harm in biobank research is linked with the processing of sensitive personal data.<sup>69</sup> Due to the potentially sensitive nature of both clinical and genetic data, there has been considerable concern regarding the possibility of privacy breaches, resulting in personal information being misused.<sup>70</sup> This is of particular relevance in the case of genetic data, as access to an individual’s biological specimens and DNA may reveal sensitive information such as predispositions to certain diseases, in addition to identity and ethnic background.<sup>71</sup> Finding ways in which to maximise the use of research data while protecting the interests of research participants is a constant challenge in the oversight of biobank research.<sup>72</sup> Absolute protection of the participant is best achieved through anonymised data in which the link between sample/data and individual identity has been irreversibly removed.<sup>73</sup> However, the potential of a biobank lies in the possibility to link genetic and biological data to medical and personal information and to re-contact donors in order to update this information.<sup>74</sup> In other words, it is necessary to be able to have the means to go back to individuals and link information on a continual basis.<sup>75</sup> There is thus increasing recognition that absolute guarantees of privacy protection can no longer be made.<sup>76</sup> Indeed, it has even been suggested

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<sup>61</sup> Elger, Bernice, S. and Arthur L. Caplan, “Consent and anonymization in research involving biobanks”, *European Molecular Biology Organization (EMBO) reports*, Vol. 7, No. 7, 2006, pp. 661-666 [p. 663].

<sup>62</sup> *Ibid*, p. 663.

<sup>63</sup> Elger et al, op. cit., 2006, p. 663.

<sup>64</sup> <https://www.personalgenomes.org/harvard>

<sup>65</sup> Lunshof et al., op. cit., 2008, p. 409.

<sup>66</sup> *Ibid*.

<sup>67</sup> Lunshof, Jeantine, E., Jason Bobe, John Aach, Misha Angrist, Joseph V. Thakuria, Daniel B. Vorhaus, Margaret R. Hoehe and George M. Church, “Personal genomes in progress: from the Human Genome Project to the Personal Genome Project”, *Dialogues in Clinical Neuroscience*, Vol. 12, No. 1, 2010, pp. 47-60 [p.55].

<sup>68</sup> *Ibid*.

<sup>69</sup> Hansson, Mats G., “The Need to Downregulate: A Minimal Ethical Framework for Biobank Research”, in Joakim Dillner (ed.), *Methods in Biobanking, Methods in Molecular Biology*, Vol. 675, 2011, pp. 39-59 [p.50].

<sup>70</sup> Hawkins et al., op. cit., 2011.

<sup>71</sup> *Ibid*, p.3.

<sup>72</sup> Gottweis et al., op. cit., 2012, p.52.

<sup>73</sup> Cambon - Thomsen, op. cit., 2004, p. 871.

<sup>74</sup> Hansson et al., op. cit., 2006, p. 267.

<sup>75</sup> Gottweis et al., op. cit., 2012, p. 52.

<sup>76</sup> Hansson et al., op. cit., 2006, p. 267.



that the issue is not about how to prevent a leak of such information, rather the steps that should be taken to mitigate the fallout.<sup>77</sup>

### 3.4 DISCRIMINATION

The issue of discrimination is closely related to data protection and privacy: breaches of data protection standards and privacy rights can have consequences that lead to discriminatory practices.<sup>78</sup> There is concern that genetic and other medical information may be used in ways that can harm individuals and their families, such as stigmatising them because of a genetic condition.<sup>79</sup> One concern in particular centres on whether the use of genetic information in the procedures of risk selection will result in limiting people's access to private health insurance.<sup>80</sup> Indeed, genetic data are viewed as being particularly sensitive. For example, the UNESCO Declaration on Human Genetic Data emphasises the "special status" of human genetic data because (i) they can be predictive of genetic predispositions concerning individuals; (ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs; (iii) they may contain information the significance of which is not necessarily known at the time of the collection of biological samples and (iv) they may have cultural significance for persons or groups.<sup>81</sup> For these reasons, "Due consideration should be given to the sensitivity of human genetic data and an appropriate level of protection for these data and biological samples should be established".<sup>82</sup> The belief that genetic information is special, justifying special consideration regarding consent and privacy is termed "genetic exceptionalism".<sup>83</sup>

### 3.5 BENEFIT-SHARING AND RETURN OF RESULTS

Large scale-biobank projects have generated ethical debate about benefit sharing and fairness in distribution of results.<sup>84</sup> In biobank research collaborations, there are multiple stakeholders in benefit sharing.<sup>85</sup> Stakeholders include the researchers themselves, the donors, non-participant citizens who have the condition being investigated and the surrounding society.<sup>86</sup> Benefit sharing among researchers has also been addressed with regard to mechanisms for promoting the sharing of bioresources.<sup>87</sup> Concerns have centred on researchers' relationship to donors and in particular their right to feedback of research results.<sup>88</sup> Individual participants

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<sup>77</sup> Brenner, Steven, E. "Be prepared for the big genome leak", *Nature*, Vol. 498, 2013, pp. 139.

<sup>78</sup> Nuffield Council on Bioethics, op. cit., 2011.

<sup>79</sup> Maschke, Karen, J, "Biobanks: DNA and Research", in Mary Crowley (ed.), *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, The Hastings Center, Garrison, NY, 2008, pp. 11-14, [p.14].

<sup>80</sup> Van Hoyweghen, Ine and Klasien Horstman, "Solidarity matters: embedding genetic technologies in private and social insurance arrangements", *New Genetics and Society*, Vol. 29, No.4, 2010, pp. 343-350 [p. 343].

<sup>81</sup> United Nations Educational, Scientific and Cultural Organization (UNESCO), "International Declaration on Human Genetic Data", Paris, 2003, [http://portal.unesco.org/en/ev.php-URL\\_ID=17720&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html)

<sup>82</sup> Ibid

<sup>83</sup> McGee, Glenn, "Foreword: Genetic Exceptionalism", *Harvard Journal of Law & Technology*, Vol. 1, No.3, 1998, pp. 565-570 [pp. 565].

<sup>84</sup> Hoeyer, op. cit., 2012, p. 216.

<sup>85</sup> Ibid, p. 216.

<sup>86</sup> Hoeyer, op. cit., 2012, p. 216.

<sup>87</sup> Cambon - Thomsen, Anne, Gudmundur A. Thorisson, Laurence Mabile et al., "The role of a bioresource research impact factor as an incentive to share human bioresources", *Nature Genetics*, Vol. 43, No. 6, June 2011, p. 503-504 [p.503].

<sup>88</sup> Hoeyer, op. cit., 2012, p. 216.

in a biobank study will generally not benefit by participating.<sup>89</sup> The purpose of such studies is to provide knowledge that may benefit a specific disease group or the population at large.<sup>90</sup> Thus private benefits are not available to research participants, however there may be research results or incidental findings that are of interest to them.<sup>91</sup> The question of return of results usually relates to informing participants about genetic predispositions, particularly in cases where treatment options or preventative strategies may be of value.<sup>92</sup> Indeed the number of findings with potential relevance to the health of individuals is expected to increase with whole-exome or whole genome sequencing.<sup>93</sup> Arguments *for* the disclosure of research results include respect for persons, beneficence, reciprocity, justice and the duty to rescue.<sup>94</sup> Arguments *against* the disclosure of research results highlight the original altruistic intention to donate materials.<sup>95</sup> For example, Stjernschantz Forsberg et al. argue that “This kind of research does not come with a duty of beneficence toward specific individuals, only an obligation to assure confidentiality and produce as much useful generalizable knowledge as possible. Returning results jeopardizes both of these aspects”. In addition, the return of results challenges the existing regulatory framework that makes a distinction between the responsibilities of clinicians and researchers; the return of results to individuals is the main concern of the clinician, while there is no such responsibility in research projects.<sup>96</sup> Indeed, conflating research and clinical care promotes a therapeutic misconception on the part of individuals who believe that they receive care when they act as research participants.<sup>97</sup> There are also practical implementation challenges that confront the biobanking community in the return of individual results.<sup>98</sup> These issues include risks to privacy and confidentiality (the return of individual findings to research participants requires that biobanks retain links to identifying information about them), legal liability issues (given that multiple entities are involved in the collection, storage, distribution and use of specimens, it will be difficult to assign responsibility for damages resulting from the return of incorrect results or inappropriate use of invalid results) and practicability and cost considerations (setting up systems to return individual research results has infrastructure implications and costs, in addition to training and education costs).<sup>99</sup>

### 3.6 OVERSIGHT BODIES AND NEW ADVISORY BODIES

#### 3.6.1. Research ethics committees

Research ethics committees (RECs) have emerged as an essential element in European biobank governance.<sup>100</sup> Any research that is carried out using samples and information from a

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<sup>89</sup> Cambon - Thomsen, op. cit., 2004, p. 872.

<sup>90</sup> Hansson, MG, “Ethics and biobanks”, *British Journal of Cancer*, Vol. 100, No.1, 2009, pp. 8-12 [p.11].

<sup>91</sup> Ibid, p.11.

<sup>92</sup> Hawkins et al., op. cit., 2011.

<sup>93</sup> Bledsoe, Marianna, J., William E. Grizzle, Brian J. Clark and Nikolajs Zeps, “Practical implementation issues and challenges for biobanks in the return of individual research results”, *Genetics in Medicine*, Vol. 14, No.4, April 2012, pp. 478-483 [p. 478].

<sup>94</sup> Ibid, p. 479.

<sup>95</sup> Stjernschantz Forsberg, Joanna, Mats G. Hansson and Stefan Eriksson, “Changing perspectives in biobank research: from individual rights to concerns about public health regarding the return of results”, *European Journal of Human Genetics*, Vol. 17, 2009, pp. 1544-1549 [p.1548].

<sup>96</sup> Gottweis et al., op. cit., 2012, p. 52.

<sup>97</sup> Viberg, Jennifer, Mats G. Hansson, Sophie Langenskiöld and Pär Segerdahl, 2013, “Incidental findings: the time is not yet ripe for a policy for biobanks”, *European Journal of Human Genetics*, Vol. 22, pp. 1-5 [p.2].

<sup>98</sup> Bledsoe et al., op. cit., 2012.

<sup>99</sup> Ibid.

<sup>100</sup> Gottweis et al., op. cit., p. 44.

biobank requires REC approval.<sup>101</sup> Moreover, the involvement of an IRB [Institutional Review Board] or REC and the need for its favourable opinion “is intended to ensure that a narrowly worded consent is not exceeded, that a consent in broader terms is not inappropriately given an even wider interpretation and that exceptional situations in which consent may be waived are not illegitimately invoked”.<sup>102</sup> In order to ensure the integration of biobanks, oversight bodies such as research ethics committees need to be proactive in cooperating with each other.<sup>103</sup> However, the decisions of research ethics committees can vary between committees, regions and countries and their powers of enforcement are limited to their own jurisdiction.<sup>104</sup> Furthermore, there is currently no mechanism for the mutual recognition of research ethics committees or a pan-European research ethics approval.<sup>105</sup> The European Forum for Good Clinical Practice (EFGCP)<sup>106</sup> works to promote good clinical practice and encourage the practice of common, high-quality standards in all stages of biomedical research throughout Europe. Initiatives such as the development of common policies and standardised procedures for European RECs also “need to be encouraged and supported for biobanking integration so that IRBs and RECs can work from a common set of standards, procedures and documentation that will streamline ethical applications without compromising the underlying ethics”.<sup>107</sup>

### 3.6.2. Data protection authorities

Due to provisions contained in Directive 95/46/EC<sup>108</sup>, data protection authorities also have an important role in overseeing data processing, both within biobanks and for the use of data and samples by researchers.<sup>109</sup> For example, data protection authorities have been empowered to identify the relevant rules for biobank research in Italy, provided guidance to stakeholders in Germany and were responsible for monitoring the creation and operation of the Health Sector Database in Iceland.<sup>110</sup>

### 3.6.3. In-house advisory bodies

A number of biobanks have created their own in-house oversight committees which typically include a scientific advisory board and data access committee.<sup>111</sup> These bodies have been viewed as essential for transparency and accountability and assuring confidence in the governance of the biobank.<sup>112</sup> The UK Biobank, for example, established an independent committee, the Ethics and Governance Council<sup>113</sup> (see section 4), to act as an independent guardian of the Ethics and Governance Framework (EGF) under which the UK Biobank

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<sup>101</sup> Ibid.

<sup>102</sup> Watson, William, R.G., Elaine W. Kay and David Smith, “Integrating biobanks: addressing the practical and ethical issues to deliver a valuable tool for cancer research”, *Nature Reviews Cancer*, Vol. 10, 2010, pp. 646-651 [p. 651].

<sup>103</sup> Ibid, p. 651.

<sup>104</sup> Gottweis et al., op. cit., p. 44.

<sup>105</sup> Ibid.

<sup>106</sup> <http://www.efgcp.eu/>

<sup>107</sup> Watson et al., op. cit., 2010, p. 651

<sup>108</sup> In 2012, the European Commission proposed a major reform of the EU legal framework on the protection of personal data. The new proposals will strengthen individual rights and tackle the challenges of globalisation and new technologies (see [http://ec.europa.eu/justice/data-protection/index\\_en.htm](http://ec.europa.eu/justice/data-protection/index_en.htm)).

<sup>109</sup> Gottweis et al., op. cit., 2012, p. 44.

<sup>110</sup> Ibid, p. 44.

<sup>111</sup> Gottweis et al., op. cit., 2012, p. 55.

<sup>112</sup> Ibid.

<sup>113</sup> <http://www.egcukbiobank.org.uk/>

operates, to advise the biobank with regard to changes in law and to safeguard the interests of research participants and the general public in relation to the project. Spanish regulation requires that biobanks include two committees of external experts, namely a scientific and an ethical committee.<sup>114</sup> The role of the committees is to report on the ethical and scientific aspects of the incorporation of existing sample collections within biobanks and to report on the transfer of samples to other biobanks or research groups.<sup>115</sup> In order to facilitate transparency, the biobank is obliged to publish the identity of the members of the external committees.<sup>116</sup> The authors note, that from a practical point of view, the existing Research Ethics Committee (REC) attached to the institution hosting the biobank might assume the role of the external ethics committee.<sup>117</sup>

Data access committees function to protect research participants' interests and to ensure that resources are not depleted or misused.<sup>118</sup> However, as noted by the authors of the Biobanks for Europe report, these bodies "may have the effect of slowing down research if a new application is needed for every new research project when samples and data are drawn from a number of biobanks for composite research projects".<sup>119</sup> For this reason, "It is important that these bodies work together with more formal oversight bodies to develop an efficient meta-level system of governance within Europe that will allow research to proceed efficiently but also will protect stakeholder interests".<sup>120</sup>

### 3.7 PUBLIC ATTITUDES AND TRUST IN BIOBANKING

Public trust is critical in determining whether people will participate in and support biobank research.<sup>121</sup> Decreased confidence in biobanking practice may have damaging consequences: "If individuals start revoking their consents the banks will not be complete, the possibility to draw scientifically valid conclusions will decrease, and the potential for follow-up examinations and medical treatment will not be fulfilled".<sup>122</sup> The process of building trust is key to all kinds of biobanking projects, irrespective of whether they rely on patient or general population studies.<sup>123</sup> Special governance frameworks for the promotion of public trust – such as the UK Biobank Ethics and Governance Council – and participatory approaches to allow donors of tissue material to have control over the use of their specimens and data have been proposed in this regard.<sup>124</sup> Embedding biobanks in well-known and long-trusted structures are also viewed as facilitating the increase of public trust due to such institutions' commitment to

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<sup>114</sup> Arias, Diaz, Javier, Maria C Martin-Arribas, Javier Garcia del Pozo and Carlos Alonso, "Spanish regulatory approach for biobanking", *European Journal of Human Genetics*, Vol. 21, 2013, pp. 708-712 [p. 709].

<sup>115</sup> Ibid.

<sup>116</sup> Arias et al, op. cit, 2013.

<sup>117</sup> Ibid.

<sup>118</sup> Gottweis et al., op. cit., 2012, p. 55.

<sup>119</sup> Ibid.

<sup>120</sup> Gottweis et al., op. cit., 2012, p. 55.

<sup>121</sup> Caulfield, Timothy, Amy L. McGuire, Mildred Cho, Janet A. Buchanan, Michael M. Burgess, Ursula Danilczyk, Christina M. Diaz, Kelly Fryer-Edwards, Shane K. Green, Marc A. Hodosh, Eric T. Juengst, Jane Kaye, Laurence Kedes, Bartha Maria Knoppers, Trudo Lemmes, Eric M. Meslin, Juli Murphy, Robert L. Nussbaum, Margaret Otlowski, Daryl Pullman, Peter N. Ray, Jeremy Sugarman and Michael Timmons, "Research Ethics Recommendations for Whole-Genome Research: Consensus Statement", 2008, *PLoS Biology*, Vol. 6, No. 3, pp. 430-435. (e73).

<sup>122</sup> Hansson op. cit., 2009, p. 8.

<sup>123</sup> Cambon-Thomsen, A., E. Rial-Sebbag and B.M. Knoppers, "Trends in ethical and legal frameworks for the use of human biobanks", *European Respiratory Journal*, Vol. 30, No.2, 2007, pp. 373-382 [p.378].

<sup>124</sup> Hansson op. cit., 2009, p. 9.

advancing scientific knowledge and serving the public interest.<sup>125</sup> Publicly funded research in universities, national research institutes and hospitals is viewed as being particularly trustworthy.<sup>126</sup> Moreover, ethical review boards and regulatory bodies that establish rules for biobank research are themselves subject to public trust.<sup>127</sup> Commercial entities involved in biobanks and biobanking research are viewed as being less trustworthy, however, with concerns relating to the inequitable distribution of benefits, biased research aims and potential misuse of personal data.<sup>128</sup>

Attitudes towards biobanks are still in flux in many countries. A report on findings of a 2010 Eurobarometer survey on the Life Sciences and Biotechnology provides insight into public perceptions of biobanks in Europe.<sup>129</sup> Strikingly, the research findings demonstrated little awareness of biobanks on the part of European citizens. Two thirds of respondents had never heard of biobanks prior to being interviewed, while only 17 per cent were described as having actively engaged in the topic, through discussions or seeking out information about biobanks.<sup>130</sup> Those better informed respondents are concentrated in Northern Europe, namely Sweden, Finland and Iceland.<sup>131</sup> Not surprisingly, there is a strong association between a country's level of engagement and the intention to participate in biobanks.<sup>132</sup> Moreover, the willingness to give broad consent is related to engagement with biobanks: the more people actively engage with biobanks, the more likely they are to agree to broad consent.<sup>133</sup> Countries such as Iceland, the Netherlands and Sweden have relatively high percentages of people who responded that one time consent was sufficient, however, this is a minority response.<sup>134</sup> The findings of the study suggest that obtaining broad consent will be a challenge for European initiatives such as BBMRI that seek coverage from different regions.<sup>135</sup>

Moreover, the analysis of the European public and biobanks underlines the importance of responsible innovation with multiple stakeholder involvement throughout the innovation cycle.<sup>136</sup> In this regard, the authors of the report highlight the importance of generating engagement among the public regarding biobanks and associated issues.<sup>137</sup>

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<sup>125</sup> Gottweis et al., op. cit., p.31.

<sup>126</sup> Ibid, p.31.

<sup>127</sup> Hansson op. cit., 2009, p. 9.

<sup>128</sup> Gaskell, George, Herbert Gottweis, Johannes Starkbaum, Monica M. Gerber, Jacqueline Broerse, Ursula Gottweis, Abbi Hobbs, Ilpo Helen, Maria Paschou, Karoliina Snell and Alexander Soulier, "Publics and biobanks: Pan-European diversity and the challenge of responsible innovation", *European Journal of Human Genetics*, Vol. 21, 2013, pp. 14-20 [p.16 ].

<sup>129</sup> Gaskell, George, Sally Stares et al., "Europeans and Biotechnology in 2010: Winds of Change", European Commission, Eurobarometer, EUR 24537, Publications of the European Union, Luxembourg, 2010.

<sup>130</sup> Ibid.

<sup>131</sup> Gaskell et al., op. cit., 2013, p. 16.

<sup>132</sup> Ibid, p.16.

<sup>133</sup> Ibid, p.16.

<sup>134</sup> Gaskell et al., 2010, p. 66

<sup>135</sup> Gaskell et al., op. cit., 2013, p. 19.

<sup>136</sup> Ibid, p.19

<sup>137</sup> Ibid, p.19.



## 4 ORGANISATIONS

The BBMRI Stakeholder's Forum gathers the input and requirements of the stakeholder community of BBMRI which includes patients, clinicians, funding organisations, associated project partners, industry and users.<sup>138</sup>

The UK Biobank Ethics and Governance Council (EGC) is an independent committee established by the Wellcome Trust and the Medical Research Council in the UK. The purposes of the EGC are: (i) to act as an independent guardian of the UK Biobank Ethics and Governance Framework (EGF)<sup>139</sup> under which the biobank functions and advise on its revisions; (ii) to monitor and report publicly on the conformity of the UK Biobank project with the EGF and; (iii) to advise more generally on the interests of research participants and the general public in relation to UK Biobank. The EGC is not the UK Biobank's internal ethics committee; rather it is an "independent, arm-length monitoring and advisory body". Moreover, "The EGC has not been established to promote or defend UK Biobank but to ensure that its actions are in conformity with the Ethics and Governance Framework".<sup>140</sup>

The Public Population Project in Genomics and Society (p3g)<sup>141</sup> is a not-for-profit consortium – funded primarily by Genome Canada, Genome Québec and CIHR - that promotes collaboration between all stakeholders involved in the field of population genomics. p3g has a number of guidelines concerning ethical aspects of population genomics.

EuroBioBank is an operating network of biobanks in Europe which provides human DNA, cell and tissue samples to scientific researchers carrying out research on rare diseases.<sup>142</sup> The aim of EuroBioBank is to create a critical mass of collections and to facilitate the exchange of biological material in order to accelerate research on these diseases. The EuroBioBank network has addressed ethical issues relating to biobanking activities and developed several documents, including an informed consent form and a material transfer form. In addition, the network provides an overview of ethical guidelines pertaining to biobanking. Ethics assessment carried out by EuroBioBank relates primarily to the assessment of research plans and practices.

The European Platform for Patients' Organisations, Science and Industry (EPPOSI) is an independent, not-for-profit, partnership-based and multi-stakeholder think-tank based in Brussels.<sup>143</sup> EPPOSI aims to discuss and influence public health policies in Europe, based on cooperative views on the part of stakeholders. In a 2006 conference, EPPOSI brought stakeholders together to discuss the future of biobanks. Representatives of several patient organisations demonstrated how their self-developed bio and databanks can lead to effective therapies for currently untreatable diseases, amongst other issues. EPPOSI issued a recommendation as a result of this conference, stressing an important role for patient organisations in biobanking and the need to educate patient organisations in relation to how to start and structure a bio-bank.

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<sup>138</sup> See <http://bbmri.eu/stakeholder-s-forum>

<sup>139</sup> The UK Biobank Ethics and Governance Framework offers a description of the standards to which the UK Biobank will operate during the creation, maintenance and use of the resource.

<sup>140</sup> See <http://www.egcukbiobank.org.uk/>

<sup>141</sup> See <http://www.p3g.org/about-p3g>

<sup>142</sup> See [http://www.eurobiobank.org/en/information/info\\_institut.htm](http://www.eurobiobank.org/en/information/info_institut.htm)

<sup>143</sup> <http://www.epposi.org/>



The Harvard Personal Genome project<sup>144</sup> aims to make a wide spectrum of data about humans accessible in order to increase biological literacy and improve human health. The Harvard Personal Genome project is supported by PersonalGenomes.org, a non-profit organisation. The PGP is at the forefront of discussion surrounding the ethical, legal and social issues (ELSI) associated with large-scale whole genome-sequencing, particularly in the area of privacy, informed consent and data accessibility, i.e., research ethics.<sup>145</sup> For example, the PGP has developed an “open consent model” (see section 3.2) which is designed to address the set of challenges associated with the creation of datasets, namely the issue of the inability to provide assurances regarding anonymity, privacy and confidentiality. The open consent model rests on a notion of veracity with regard to all aspects of participation.

The HUGO Committee on Ethics, Law and Society<sup>146</sup> is part of the Human Genome Organisation,<sup>147</sup> an international organisation populated by scientists involved in human genetics. The purposes of the HUGO Ethics Committee are as follows: (i) to promote discussion and understanding of social, legal and ethical issues as they relate to the conduct of, and the use of knowledge derived from, human genome research; (ii) to act as an interface between the scientific community, policy-makers, educators and the public; (iii) to foster greater public understanding of human variation and complexity; (iv) to collaborate with other international bodies in genetics, health and society with the goal of disseminating information; (v) to deliberate about policy issues in order to provide advice to the HUGO council and to issue statements where appropriate; and (vi) to report on its activities at least annually to the HUGO Council and to act on any other related matter. In 2002, the HUGO Ethics Committee issued a statement on Human Genomic Databases<sup>148</sup>, declaring human genomic databases to be global public goods to be enjoyed by everyone worldwide with no groups excluded.

In 2011/2012, the Executive Board of the Research Council of Norway launched a programme which aims to take full advantage of Norway’s population-based health surveys, biobanks and national health registers. The Programme on Human Biobanks and Health Data (BIOBANKS)<sup>149</sup> runs until 2016 and aims to generate novel research-based knowledge aimed at the prevention, detection, diagnosis and treatment of somatic and psychiatric diseases. Each project addresses ethical, legal and social aspects (ELSA) relating to the use of human biological material and health data in the project and such aspects may also be included as a sub-project or activity<sup>150</sup>.

GeneWatch UK<sup>151</sup> is a not-for-profit policy research and public interest group which investigates the ways in which genetic science and technologies impact on food, health, agriculture, environment and society. GeneWatch aims to increase public understanding of genetic technologies and to secure public, academic, media, investor, regulatory, parliamentary, local, national and international governments’ support for a comprehensive programme to ensure genetic technologies are developed and used in a safe and ethical

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<sup>144</sup> <https://www.personalgenomes.org/harvard>

<sup>145</sup> Lunshof et al., op. cit., 2010, p. 55

<sup>146</sup> [http://hugo-international.org/comm\\_hugoethicscommittee.php](http://hugo-international.org/comm_hugoethicscommittee.php)

<sup>147</sup> <http://hugo-international.org/aboutus.php>

<sup>148</sup> The Human Genome Organisation (HUGO). HUGO Ethics Committee: Statement on Human Genomic Databases. 2002, [http://www.hugo-international.org/img/genomic\\_2002.pdf](http://www.hugo-international.org/img/genomic_2002.pdf)

<sup>149</sup> [http://www.forskingsradet.no/prognett-biobank/Nyheter/Human\\_biobanks\\_and\\_health\\_data/1253973285816/p1253972330079](http://www.forskingsradet.no/prognett-biobank/Nyheter/Human_biobanks_and_health_data/1253973285816/p1253972330079)

<sup>150</sup> [http://www.forskingsradet.no/prognett-elsa/Home\\_page/1224698247023](http://www.forskingsradet.no/prognett-elsa/Home_page/1224698247023)

<sup>151</sup> <http://www.genewatch.org/sub-396416>

manner. GeneWatch has investigated biobanks, and in particular, the UK Biobank. Genewatch's main concerns about the UK Biobank since it was first proposed, include the role of commercial companies in the enterprise and the lack of safeguards to protect participants from future misuse of their genetic information.<sup>152</sup> More recently, in January 2014, in its response to the Nuffield Council on Bioethics consultation on the linking and use of biological and health data<sup>153</sup>, GeneWatch voiced its concerns about the proposal in relation to issues including the ethical implications of genomic surveillance and the right of the public to control their own medical records, DNA and genomes, and other personal information.<sup>154</sup>

## 5 Institutionalisation

In order to understand the degree of institutionalisation of ethics assessment of biobanking, we turn to literature on the governance of biobanking - as ethics is an integral part of governance - and, in particular, two recent publications which outline the current state of affairs in the governance of biobanking.

Discussion of the governance framework for biobanking in Europe tends to take place within the context of the pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), a collaboration of key European biobanks. According to the Biobanks for Europe report,<sup>155</sup> while the Member States of the European Union are world leaders in the development of biobanking infrastructure to support research, the governance framework needs to be strengthened in order to adequately support the new infrastructure development.<sup>156</sup> A well-known challenge in the field is the fact that the implementation of relevant ethical guidelines and legal instruments differ significantly across countries, impeding international collaboration and exchange of information.<sup>157</sup> Moreover, national research ethics committees may have different requirements for collaborative research, with potential implications for research consortia wishing to share samples and data derived from different data banks. As stated in section 3.6.1, there is, at present, no facility for research ethics approval at the pan-European level, leading to duplication of oversight and compliance, an inability to investigate non-compliance with requirements due to jurisdictional issues, with the possible effect of slowing down the research process and the attractiveness of using biobanks.<sup>158</sup>

The report highlights the importance of new advisory bodies attached to biobanks and data access committees working with more formal oversight bodies such as international organisations representing practitioners (e.g., EuroBioBank and the International Society of Biological and Environmental Repositories) “to develop an efficient meta-level system of governance within Europe that will allow research to proceed efficiently but will also protect stakeholder interests”.<sup>159</sup> Rial-Sebbag and Cambon-Thomsen argue that new forms of governance – such as that facilitated by the BBMRI - at a supranational level allow “a large

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<sup>152</sup> See [http://www.genewatch.org/article.shtml?als\[cid\]=507674&als\[itemid\]=541998](http://www.genewatch.org/article.shtml?als[cid]=507674&als[itemid]=541998)

<sup>153</sup> See <http://www.nuffieldbioethics.org/biological-and-health-data/biological-and-health-data-consultation-linking-and-use-biological-and-he>

<sup>154</sup> See [http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Nuffieldbiodata\\_GWresponse\\_fin2.pdf](http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Nuffieldbiodata_GWresponse_fin2.pdf)

<sup>155</sup> Gottweis et al., op. cit., 2012, p. 5.

<sup>156</sup> Ibid, p. 5.

<sup>157</sup> Gottweis et al., op. cit., 2012, p. 6.

<sup>158</sup> Gottweis et al., op. cit., 2012, p. 48.

<sup>159</sup> Ibid, p. 56

role for ethical reflection in the absence of collectively applicable legal rules”.<sup>160</sup> Although the scope of ethical reflection at European level differs and the elements necessary for an acceptable use of samples vary from state to state, the authors see a new ‘organizational ethics’ emerging:

This new form of ethics will embody new features: more flexible than the law and less technical than the standard, it is certainly an intermediate norm to be referred to for constant adaptation to the needs of regulation in the field of biobanks. This new approach emphasizes the limits of legal harmonization because of the technical limitations posed by the legal instruments themselves, and it allows space for normative creativity. The only proposals that can be made for a ‘harmonization of ethics’, understood as a tool of governance, should be based on these common principles for the protection of participants, taking into account specific issues relating to biobanks (definition, informed consent, transfer samples and data, future uses, and so on) and, more particularly, should take into consideration the involvement of the public.<sup>161</sup>

## 6 INTERNATIONAL FRAMEWORKS AND PROTOCOLS

Council for International Organizations of Medical Sciences (CIOMS), “International Ethical Guidelines for Biomedical Research Involving Human Subjects”, World Health Organization, Geneva, 2002.<sup>162</sup>

A Working Group is currently working to revise the CIOMS guidelines. The document was last revised in 2002 and since then, several developments have taken place, both in the field of biomedical research itself and in the field of research ethics. The group will present first drafts of the revised guidelines at the World Congress of the International Association of Bioethics in Mexico in June 2014.

World Medical Association Declaration on Ethical Considerations regarding Health Databases, 2002.<sup>163</sup>

This declaration sets out principles for all new and existing health databases, including those run and managed by commercial organisations. Principles include access to information by patients, confidentiality, patients’ consent, de-identified data, data integrity, documentation, management and policies.

Council of Europe, Recommendation Rec (2006) 4 of the Committee of Ministers to member states on research on biological materials of human origin.<sup>164</sup>

Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research. Strasbourg, 2005.<sup>165</sup>

European Society of Human Genetics, “Data storage and DNA banking for biomedical research: technical, social and ethical issues”, 2001.<sup>166</sup>

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<sup>160</sup> Rial-Sebbag, Emmanuelle and Anne Cambon-Thomsen, “The emergence of biobanks in the legal landscape: Towards a new model of governance”, *Journal of Law and Society*, Vol. 39, No.1, 2012, pp. 113-130 [p. 127].

<sup>161</sup> Ibid, p. 128.

<sup>162</sup> [http://www.cioms.ch/publications/layout\\_guide2002.pdf](http://www.cioms.ch/publications/layout_guide2002.pdf)

<sup>163</sup> <http://www.wma.net/en/30publications/10policies/d1/>

<sup>164</sup> <https://wcd.coe.int/ViewDoc.jsp?id=977859>

<sup>165</sup> <http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm>

World Health Organization, “Genetic Databases: Assessing the Benefits and the Impact on Human and Patient Rights – a World Health Organization Report”, 2003.<sup>167</sup>

This article summarises the underlying rationale and provisions of a report on genetic databases prepared for the European Partnership on Patients’ Rights and Citizens’ Empowerment, a network of the World Health Organisation Regional Office for Europe. This article provides recommendations based on the outcomes of the Working Group for the ethical, legal and social considerations of the creation and operation of genetic databases comprising human genetic materials.

International Society for Biological and Environmental Repositories, “2012 Best Practices for Repositories: Collection, Storage, Retrieval, and Distribution of Biological Materials for Research”, International Society for Biological and Environmental Repositories, 2012.<sup>168</sup>

The European Group on Ethics in Science and New Technologies, “Ethical aspects of human tissue banking”, 1998.<sup>169</sup>

Organisation for Economic Co-operation and Development (OECD), “Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs)”, 2009.<sup>170</sup>

United Nations Educational, Scientific and Cultural Organization (UNESCO), “International Declaration on Human Genetic Data”, Paris, 2003.<sup>171</sup>

#### *National frameworks*

The United Kingdom’s Medical Research Council Human Tissue and Biological Samples for use in Research – Operational and Ethical guidelines.<sup>172</sup>

This document – issued in 2001 - offers guidance for those working with human tissue and includes Human Tissue legislation summaries. The main audience for this is policymakers.

Deutscher Ethikrat (German Ethics Council), “Human Biobanks for Research: Opinion”, 2010.<sup>173</sup>

National Bioethics Advisory Commission, “Research Involving Human Biological Materials: Ethical Issues and Policy Guidance”, Rockville, Maryland, USA, 1999.<sup>174</sup>

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<sup>166</sup> <https://www.eshg.org/eshgdocs.0.html>

<sup>167</sup> <https://www.era.lib.ed.ac.uk/handle/1842/2447>

<sup>168</sup> <http://c.ymcdn.com/sites/www.isber.org/resource/resmgr/Files/2012ISBERBestPractices3rdedi.pdf>

<sup>169</sup> [http://ec.europa.eu/bepa/european-group-ethics/docs/avis11\\_en.pdf](http://ec.europa.eu/bepa/european-group-ethics/docs/avis11_en.pdf)

<sup>170</sup> <http://www.oecd.org/science/biotech/guidelinesforhumanbiobanksandgeneticresearchdatabaseshbgrds.htm>

<sup>171</sup> [http://portal.unesco.org/en/ev.php-URL\\_ID=17720&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html)

<sup>172</sup> <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420>

<sup>173</sup> [http://ec.europa.eu/research/biosociety/pdf/ethikrat\\_opinion\\_biobanks.pdf](http://ec.europa.eu/research/biosociety/pdf/ethikrat_opinion_biobanks.pdf)

<sup>174</sup> <https://bioethicsarchive.georgetown.edu/nbac/hbm.pdf>

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- *Nature Reviews Genetics*<sup>175</sup>
- *The New England Journal of Medicine*<sup>176</sup>
- *Annual Reviews of Genomics and Genetics*<sup>177</sup>
- *New Genetics and Society*<sup>178</sup>
- *Norsk Epidemiologi – Norwegian Journal of Epidemiology*<sup>179</sup>
- *Journal of Law and Society*<sup>180</sup>
- *Sociology of Health and Illness*<sup>181</sup>
- *Social Science and Medicine*<sup>182</sup>
- *Genomics, Society and Policy*<sup>183</sup>
- *Biopreservation and Biobanking*<sup>184</sup>
- *Centre for Research Ethics & Bioethics (CRB), Biobank Ethics Report: Approaching Future Issues*, Uppsala University, 2012.

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<sup>175</sup> <http://www.nature.com/nrg/index.html>

<sup>176</sup> <http://www.nejm.org/>

<sup>177</sup> <http://www.annualreviews.org/loi/genom>

<sup>178</sup>

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<sup>179</sup> <https://www.ntnu.no/ojs/index.php/norepid/index>

<sup>180</sup> [http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1467-6478](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1467-6478)

<sup>181</sup> [http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1467-9566](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1467-9566)

<sup>182</sup> <http://www.journals.elsevier.com/social-science-and-medicine/>

<sup>183</sup> <http://www.gspjournal.com/>

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