

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *The linking and use of biological and health data* between 17 October 2013 and 10 January 2014. The views expressed are solely those of the respondent(s) and not those of the Council.

Dr Atina Krajewska
Law Lecturer
Cardiff Law School
Email: Krajewskaa@cardiff.ac.uk

The linking and use of biological and health data

Consultation response by

Dr Atina Krajewska and Prof. Ruth Chadwick

Consultation question 1:

Do biomedical data have special significance?

Possible aspects to consider:

- Is it useful (or even possible) to define biomedical data as a distinct class of data? If it is, what are the practical and ethical implications of different ways of defining this class?
- What factors contribute to the belief that personal biomedical data deserve special protection? Does the sensitivity of biomedical data depend entirely on context or do biomedical data have special attributes that make them intrinsically more sensitive than other kinds of data?
- How are changes in the scope of the data in use providing meaningful insights into individual biological variation and health?
- Do some sub-sets of biomedical data (such as genomic [data sets](#)) present particular ethical challenges or offer ethically important benefits?
- To what extent should genomic data sets be regarded as belonging to one individual and to what extent should other interests (e.g. of family members sharing genomic sequences) be recognised? What implications might this have for consent to collection of such data, for feedback concerning the data and for its broader use?

1.1. Defining biomedical data

The first issue that needs to be addressed when answering this question is about the definition of ‘biomedical data’. Traditionally personal data protection legislation has used terms such as ‘medical-’ or ‘health data’, and in the new proposal for EU Regulation on the protection of personal data, also genetic data. Art. 4 of the proposed Regulation provides for the following definitions:

(10) ‘Genetic data’ means all data, of whatever type, concerning the characteristics of an individual which are inherited or acquired during early prenatal development;

(11) ‘Biometric data’ means any data relating to the physical, physiological or behavioural characteristics of an individual which allow their unique identification, such as facial images, or dactyloscopic data;

(12) ‘Data concerning health’ means any information which relates to the physical or mental health of an individual, or to the provision of health services to the individual;

Thus, the question occurs, whether there is a reason and a need for introducing a new term ‘biomedical data’ in this context. If the EU Regulation is adopted and it seems that this will be finalized in the near future, it will be directly applicable and effective in domestic laws of all member states. An argument in favor of using the term ‘biomedical data’ is that it could perhaps be linked to the Council of Europe Convention on Human Rights and *Biomedicine* and its accompanying Additional Protocols which speak of ‘biomedicine’ and ‘biomedical research’. This terminology was justified by the fact that the Convention aimed at regulating issues concerning ‘the application of biology and medicine’, which were at the forefront of science at the time. The same rationale seems to apply to the terminology chosen in the consultation document. The term is indeed very broad and could be said to encompass genetic, biometric and health data mentioned in the EU Regulation proposal, and as such it is very appealing. However, should a special protection of these types of data be advocated the question arises whether introducing a new terminology will not add another level of complexity to the data protection legislation.

An additional issue that needs to be considered in the context of existing legal frameworks is the way in which the new approach focused on biomedical data will deal with the fact that several international and national initiatives still operate within the ‘genocentric dogma’¹.

¹ A. Rouvroy, *Human Genes and Neoliberal Governance. A Foucauldian Critique*, Routledge-Cavendish 2008, 27. Also: S. Huang, “The practical problems of post-genomic biology”, **18** *Nature Biotechnology* (2000), 471 –

There is a growing body of legislation dealing specifically with genetic testing and DNA banks, including the Swiss Federal Law on the Genetic Testing of Humans (2004)², the US Genetic Information Non-discrimination Act (GINA 2008)³, and the German *Gendiagnostik-Gesetz* (2009)⁴, the Portuguese Law no. 12/2005 on personal genetic information and information regarding health⁵). Although this trend in itself is not a sufficient reason to abandon attempts to address the changes occurring in the new environment, a comparative analysis of different definitions aiming at definitional clarity should be undertaken as part of any regulatory project. For example, the title of the consultation mentions biological and health data separately and the question occurs how *biomedical*, *biological* and *health* data should be differentiated in practice. In the context of the current privacy legislation health data are regarded as sensitive and as such can only be processed in exceptional circumstances. Thus, the crux of Question 1 is whether biological data should be seen as special (sensitive) too.

1.2. Special protection of biomedical data

Question 1 resonates with past debates about the genetic exceptionalism.⁶ The proponents of the latter focused on the fact that DNA helps: a) identify individuals, b) predict their future health, and c) draw conclusions about family members, and populations, d) confirms with unprecedented precision their uniqueness and constitutes a reason for a special data protection. Due to the familial character of the information, the use of genetic data was to be governed by separate provisions relating to consent and confidentiality, which would take into account the rights of family members. The idea resulted in a series of instruments, adopted by various international human rights organisations, including the UN, UNESCO,

472 and J. Calvert, “The Commodification of Emergence: Systems Biology, Synthetic Biology and Intellectual Property”, 3 *Biosocieties* (2008), 383-398.

² Bundesgesetz über genetische Untersuchungen beim Menschen (GUMG), 8.10.2004, AS 2007 635, entered into force only recently 1.04.2007. Available via: http://www.admin.ch/ch/d/sr/c810_12.html.

³ Available via: <http://www.govtrack.us/congress/billtext.xpd?bill=h110-493&show-changes=0&page-command=print>;

⁴ Gesetz über genetische Untersuchungen bei Menschen (Gendiagnostikgesetz - GenDG), 31.07.2009 BGBl. I S. 2529, 3672; in force 1.02.2010, available via: <http://www.buzer.de/gesetz/8967/index.htm>.

⁵ Privileged Project. “Privacy in law, ethics and genetic data”, *Genetic databases and Biobanks by Country*, available via: <http://www.privileged.group.shef.ac.uk/projstages/stage-2-genetic-databases-and-biobanks/genetic-databases-and-biobanks-by-country/portugal>

⁶ *Supra* note 8.

WMA, and the Council of Europe.⁷ The ‘exceptionalist paradigm’⁸ has been criticised for its significant flaws⁹ and recently also considerably undermined by advances in life sciences¹⁰.

There are several points that need to be made here. First of all, it seems that the notion of biomedical data addresses many points of contention expressed with regard to genetic exceptionalism. It parts with the distinction between genetic and non-genetic factors - a distinction which is clearly not the crucial one.¹¹ Placing emphasis on genetic determinants might result in the reinforcement of genetic stigmatization and exclusion¹², since the perception of genetics and genomics is burdened by misconceptions of biological determinism and reductionism¹³. Therefore, it has been claimed that general legal standards are more effective in dealing with these problems than genetic-specific laws.¹⁴ The notion of biomedical data does not require separating ‘genetic’ information from other ‘health’ information and it seems to suggest the same level of legal protection of personal data in the course of data processing for medical and research purposes. An X-ray photograph of a person’s teeth, found on the street, would not count as personal data unless linked with other information. More importantly, the notion of biomedical data acknowledges the fact that information required to build an organism is distributed over many levels of biological and external organization.¹⁵ The claim gains gravity in light of the latest developments mentioned

⁷ Among them there were the WMA Declaration on the Human Genome Project (1992), the 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) and the Recommendation on the protection of medical data (97)5, the two UNESCO Declarations on Human Genome and Human Rights (1997) and Human Genetic Data (2003), and finally the UN Declaration on Human Cloning (2005).

⁸ They include: the Council of Europe Additional Protocol to Convention on Human Rights and Biomedicine on Genetic Testing for Health Purposes (2008), available via:

<http://conventions.coe.int/Treaty/EN/Treaties/html/203.htm>; *EuroGentest*, available via:

<http://www.eurogentest.org/> retrieved 15 May 2010; and the Public Population Project on Genetics (P3G),

available via: <http://www.p3gconsortium.org/>, retrieved 15 May 2010. A notable exception seems to be the OECD Draft Guidelines for Human Biobanks and Genetic Research Databases (2009) that focus on ‘biological’ instead of genetic data. Available via:

http://www.oecd.org/document/12/0,3343,en_2649_34537_40302092_1_1_1_1,00.html;

⁹ For a summary of the discussion see: A.Krajewska, “Conceptual quandaries about genetic data – a comparative perspective”, *European Journal of Health Law* 16 (2009), 7-26.

¹⁰ E.F. Keller, *The Century of the Gene*, Harvard University Press 2000, 5.

¹¹ T. Murray, “Genetic Exceptionalism and Future Diaries: Is Genetic Exceptionalism Different From Other Medical Information?”, in: Rothstein (ed.), *Genetic Secrets: Protecting Privacy and Confidentiality*, Yale University Press 1997, 60.

¹² L.O. Gostin and Hodge Jr., “Genetic Privacy and the Law: An End to Genetic Exceptionalism”, (1999) 40 *Jurimetrics: journal of law, science and technology* No. 21, 21-58.

¹³ J. Dupré, *The Disorder of Things. Metaphysical Foundations of the Disunity of Science* (Cambridge, Harvard University Press, 1996), 121.

¹⁴ M.A. Rothstein, “Genetic Exceptionalism and Legislative Pragmatism”, 35 *The Hastings Centre Report*, 2005, 27-33, 30.

¹⁵ J. Dupré, *Darwin’s Legacy. What Evolution Means Today*, (Oxford University Press, London, 2003), p. 23-25

in this consultation (-omics, big data, algorithms, etc...), which are based on the integration of different data types and methods.¹⁶ This is what makes the approach based on biomedical data (rather than genetic data) so appealing.

Nevertheless, several points require further consideration here. First and foremost, what makes the new developments special is not the fact that inherently new data are created, but the new context in which data are generated and processed: its scale and complexity. It is the scale, complexity and the time-sensitivity of the systems generating the data that is unprecedented.

A well-known and extensively discussed problem stemming from these changes is the issue of anonymity.¹⁷ At the moment the regulatory design is based on a principle that, as long as data remain unidentifiable, they are not seen as ‘personal data’, hence, privacy or data protection laws will not apply.¹⁸ Anonymisation of data (making them non-identifiable) is the most common method of privacy risk assessment in medical research. However, as pointed out by Heeney et al., little consideration is taken of the existence of the ‘data environment’.¹⁹ Although genomic data is high resolution and therefore more likely than socio-economic data to provide a combination of traits that are individually unique, it is the existence of other data sets and resources that increase the likelihood of (re-)identification by interference. In 2008 and 2009 the *Public Library of Science (PLOS) Genetics* published a series of statistical studies establishing that an individual could be identified in aggregate data, as genome-wide scans provide such a wide range of unique data points.²⁰ The ability to combine different datasets exacerbates the problem.²¹

¹⁶ The integration of transcriptomic, proteomic and metabolomic data provides a more systems-wide view of the cell state than one type of data can.

¹⁷ There are also difficulties with regard to interpretation of different terminologies including anonymous, anonymized and coded data, which are used internationally and transnationally in different legal documents.

¹⁸ J.E. Lunshof et al., 406-407.

¹⁹ C. Heeney, N. Hawkins, J. de Vries, P. Boddington, J. Kaye (2010) “Assessing the Privacy Risks of Data Sharing in Genomics”, *Public Health Genomics*, 29.03.2010, available via: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2872768/>

²⁰ N. Homer, Szelinger S, Redman M, Duggan D, Tembe W, et al., (2008) Resolving individuals contributing trace amounts of DNA to highly complex mixtures using high-density SNP genotyping microarrays. *Public Library of Science Genetics* 4(8): e1000167; R. Braun, Rowe W, Schaefer C, Zhang J, Buetow K (2009) “Needles in the haystack: identifying individuals present in pooled genomic data”. *PLoS Genet* 5(9): e1000668; PM Visscher, Hill WG (2009) “The limits of individual identification from sample allele frequencies: theory and statistical analysis”. *PLoS Genet* 5(9): e1000628. R. Braun, Rowe W, Schaefer C, Zhang J, Buetow K (2009) “Needles in the haystack: identifying individuals present in pooled genomic data”. *PLoS Genet* 5(9): e1000668; PM Visscher, Hill WG (2009) “The limits of individual identification from sample allele frequencies: theory and statistical analysis”. *PLoS Genet* 5(9): e1000628.

²¹ Gymrek et al., Identifying Personal Genomes by Surname Inference, *Science* 18 January 2013: Vol. 339 no. 6117 pp. 321-324 DOI: 10.1126/science.1229566.

As pointed out earlier, genomic sequence data is being generated at an ever increasing rate: by private companies offering consumer genetic testing, ancestor tracing companies, by researchers from public and private sector who widely share data retrieved from different projects.²² Furthermore, where archived biological research samples are reused for genomic research, the participant may be unaware that their DNA is part of a genomic research and its implications for privacy.²³ Finally, in a digital age, due to new technologies and multiple overlapping data sources, ‘once genomic data is publicly released, it is virtually impossible to retrieve it or make it private again, or even know who has the information or to what use it is being put.’²⁴ The need for new approaches has been also recently acknowledged by the Science and Trust Expert Group, who suggested that healthy but informed scepticism is preferable to a society where people blindly and unquestionably trust sciences and scientists, and that the government should take a better account of risk and uncertainties in policy making.²⁵

One of the biggest benefits and risks of the new technologies is that they aim at providing a global and unique description of the organism.²⁶ Systems medicine serves as an example of this change. It views organisms as integrated and interacting networks of genes, proteins and biochemical reactions which give rise to life.²⁷ Through combined efforts of biology, informatics and engineering, systems biology makes it possible to establish new links between the vast amount of genomic, phenotypic and environmental information. It focuses on the interactions between them taking into consideration new factors such as context, time and space.²⁸ Its supporters hope that in the future it will lead to individualized, time- and space-sensitive medicine, with minimized interventions and preventive treatments²⁹, which

²² E.g. Human Genome Project, HapMap Project, 1000 Genomes Project, European Genotype Archive.

²³ This is because: a) data protection laws do not require consent as long as the data is non-identifiable, the aim of data processing is legitimate and the processing takes place within health care system or medical research. The problem is exacerbated by the fact that European legal systems reject property rights over body parts.

²⁴ C. Heeney et al., *supra* note, 6.

²⁵ Department of Business, Innovation and Skills, “Starting a National Conversation about Good Science”, London, March 2010, available via: <http://interactive.bis.gov.uk/scienceandsociety/site/trust/2010/03/08/new-science-and-trust-expert-group-report-starting-a-national-conversation-about-good-science/2010>, accessed on 27.08.2010.

²⁶ See: M. Morange, “Post-Genomics, between Reduction and Emergence”, 151 *Synthese* 3(2006), New Perspectives on Reduction and Emergence in Physics, Biology and Psychology, 355-360, 356.

²⁷ Institute for Systems Biology, “Systems Biology: the 21st Century Science”, retrieved June 30, 2008 http://www.systemsbiology.org/Intro_to_ISB_and_Systems_Biology/Systems_Biology_-_the_21st_Century_Science.

²⁸ A.C. Ahn, M. Tewari, Ch.-S. Poon, R.S. Phillips, The limits of reductionism in Medicine: Could systems Biology Offer an Alternative?, 3 *PLOS Medicine*, No. 7, July 2006, 0709.

²⁹ M. Cassman et al., Barriers to progress in systems biology, *Nature* 2005/438, 1079. Also in: Ahn, Tewari, Poon, Phillips, ‘The Clinical Applications of a Systems Approach’, (July 2006) 3 *PLOS Medicine*, No. 7, 0959.

will take into account the ‘interactive, distributed regulation’ and the ‘continuous transformation’ of an organism.³⁰ The biggest challenge stemming from these developments is that it is becoming increasingly difficult, almost impossible, to distinguish between the data itself and the technologies that generate it, especially in terms of their value and sensitivity. If we were to focus on the biomedical data as such rather than the integration of data sets and programmes enabling their continuous processing, we would have to deal with the problem (analogous to the discussions about genetic *exceptionalism*) that biomedical data are not a homogenous category, as their penetrance and susceptibility to disease vary substantially from one condition to another, from one event of data processing to another. Following this line of reasoning sub-sets of biomedical data might have the potential to become highly sensitive if they: a) reveal predictive information, b) enable the identification of the individual research subject (patient), c) their use can lead to discrimination of individuals or groups, d) negatively affect equitable access to health care. What is, however, important to underline is that no sub-set of data (be it genetic, proteomic, metabolomic) is sensitive in itself. What is special and will require a major shift in the regulatory framework of data protection laws is the scale of the data coupled with complexity, flexibility and dynamism of computer programmes.

Consultation question 2:

What are the new privacy issues?

Possible aspects to consider:

- Do new information technologies and [‘big data’](#) science raise privacy issues that are new in kind or in scale? (See above)
- What are the implications for individual anonymity of linking data across large numbers of databases? (See above)
- What is the ‘public interest’ in biomedical data? What benefits do we want to obtain? In what circumstances might the public interest take precedence over individual and minority group interests?

³⁰ S. Oyama, P. E. Griffiths, and Russell Gray (ed.), *Cycles of Contingency: Developmental Systems and Evolution*, MIT Press 2001.

- What are the actual harms we should seek to avoid in using biomedical data (e.g. discrimination, stigmatisation)? What evidence is there of these harms having occurred?
- In what ways does it matter if people's data are used in ways of which they are unaware but that will never affect them?
- How are applications of computer-based technology (e.g. social networking, image sharing, etc.) affecting concepts of privacy, identity and social relatedness? How are related behavioural norms influenced (e.g. willingness to share and publish data)?
- Would it be helpful to treat biomedical data as 'property'?

2.1 Public Interest

The benefits of the use of biomedical data in research and in medical practice for individual and society have been numerous. The combined efforts of genomics, mathematics, and engineering make it possible to establish new links between the vast amount of genomic, phenotypic and environmental information in hope that it will lead to individualized, time- and space-sensitive treatments, and minimized interventions.³¹ Although it remains to be seen how far the field has to go before it achieves the capacity for prediction and control, there is no doubt that the quantity of data it is already integrating constitutes yet another shift in molecular life sciences.³² The development of next-generation DNA mega-sequencing technologies makes it possible to sequence and assemble a human genome in a matter of weeks at a relatively low price (£655).³³ In addition, according to a recent OECD report, genetic testing is likely to shift from identifying single genetic mutations to tests for multiple genes.³⁴ Genomics is already being integrated into routine clinical care.³⁵ Genetic tests that help indicate risk for adverse health conditions, including Type 1 & 2 Diabetes, breast and prostate cancer, Alzheimer's disease, obesity, and many more are already available on the

³¹ M. Cassman et al., Barriers to progress in systems biology, *Nature* 2005/438, 1079. Also in: Ahn, Tewari, Poon, Phillips, 'The Clinical Applications of a Systems Approach', (July 2006) 3 *PLOS Medicine*, No. 7, 0959.

³² M. O'Malley, J. Calvert, J. Dupre, 'The study of societhical issues in systems biology', 7 *The American Journal of Bioethics* 4 (2007), 70-71.

³³ Ch. Auffray, Z. Chen, L. Hood, 'Systems medicine: the future of medical genomics in healthcare', 1 *Genome Medicine* 1 (2009), 2-4.

³⁴ OECD, "Human Health Biotechnologies to 2015", *OECD Journal* 2009/3, p. 171.

³⁵ A.L. McGuire, MK Cho, S.E. McGuire, T. Caufield, "The Future of Personal Genomics", *Science*, 21/09/2007, 317(5845):1687.

market directly to consumers.³⁶ For example, the advent of microarray technology, which enabled the development of Genome-Wide Association Studies (GWAS), has transformed the landscape of dementia research.³⁷ These techniques allow geneticists to sequence a large number of genes simultaneously, in a hypothesis-free manner. For the first time in the history of human genetics research, the genetic basis of AD and other heritable diseases can be assessed in unprecedented detail and efficiency. In the course of only three years, they delivered several additional Alzheimer's Disease (AD) susceptibility *loci* that are common in the general population, but which only exert very small genetic effects.³⁸ Several other common risk-factor genes can be expected to emerge from GWAS in the near future. The approach is particularly attractive for other disorders with overlapping phenotypes, such as frontotemporal dementia.³⁹ Although these techniques still need to be validated before routine clinical use they might transform the concept of genetic testing and constitute a major step towards personalised medicine.⁴⁰ These changes will certainly affect the way in which risk of developing dementia is assessed by insurers in future.

The utility of most of the information obtained from these tests is likely to be limited in the near future and will generate new clinical and ethical dilemmas (e.g. interpretation of rare and novel variants). Usually the only advice doctors can give to their patients concerns life style choices such as food, drink and exercise. Also, simply knowing genetic risks and disease predispositions may not lead to better health decisions. While unlike cancer – predictive information about cancer might have therapeutic consequences, information about dementia does not allow for health-related behavioural risk modification.⁴¹ Furthermore, it may be extremely difficult to distinguish between genuinely useful and irrelevant, misleading, and

³⁶ On the 11th May 2010 *Pathway Genomics* announced that it is to sell such kits in a national chain of pharmacies across the US. Shortly after, the US Food and Drug Administration made a move to restrict direct-to-consumer genetic test offerings and the UK Human Genetic Commission issued guidance for future regulation. See: R. Stein, 'Company plans to sell genetic testing kit at drugstores', *Washington Post*, 11.05.2010, available via: <http://www.washingtonpost.com/wp-dyn/content/article/2010/05/10/AR2010051004904.html> and The Human Genetics Commission, A Common Framework of Principles for direct-to-consumer genetic testing services, London, August 2010, available via: <http://www.hgc.gov.uk/Client/document.asp?DocId=280&CAtegorYId=10>. Also reported by: C. Wright, FDA grapples with regulation of DTC genetic tests, *PHG Foundation News*, 26/07/2010, available via: <http://www.phgfoundation.org/news/5590/>

³⁷ L Bertram, CM Lill, RE Tanzi, 'The genetics of Alzheimer disease: back to the future' (2010) 68 *Neuron Review* 2, 270-81. doi: 10.1016/j.neuron.2010.10.013.

³⁸ L Bertram, CM Lill, RE Tanzi, 'The genetics of Alzheimer disease: back to the future' (2010) 68 *Neuron Review* 2, 270-81. doi: 10.1016/j.neuron.2010.10.013.

³⁹ See: C T Loy, P R Schofield, A M Turner, J B Kwok, Genetics of dementia, *The Lancet*, 6/08/2013, [http://dx.doi.org/10.1016/S0140-6736\(13\)60630-3](http://dx.doi.org/10.1016/S0140-6736(13)60630-3).

⁴⁰ RP Lifton, Individual genomes on the horizon, *New England Journal of Medicine*, 2010; 362:1235-36.

⁴¹ P J Morrison, Insurance, unfair discrimination, and genetic testing, 366 *The Lancet*, 10/09/2005, 877-879

even harmful information. Furthermore, there are questions of accuracy and quality of data which should not be ignored. This brings back the issue of access to such testing, proper counselling, and the development of the secure bioinformatic and IT systems.

2.2. Possible harms, discrimination and stigmatisation

Debates about the risks of discrimination and stigmatisation stemming from the use of biomedical data can be reasonably expected to reflect the debates about genetic discrimination. Critics have long been arguing that it is more a matter of perception and fear than a real phenomenon.⁴² However, recent research (triangulated approaches and validation studies) conducted in Australia, Canada, the US, and Europe seems to suggest that genetic discrimination is now an established, incontrovertible ethical, legal, and psychosocial phenomenon.⁴³ These findings suggest that in the context of large data-sets (combining genetic, epidemiological and other health and biological data) the risk of discrimination will increase. The increase is related to two main factors. The first factor is the scale and complexity of the data sets and systems makes it more difficult to control the flow of data, hence increasing the potential for abuse. The second factor is the commercialisation of medicine and science and the shift (at least in the UK) from public to private enterprise in health care. At the same time, it is worth noticing that the risks will not be exclusively linked to commercialisation, but it can occur as a result of the use of data by state institutions (*S and Marper v UK* [2008]).

It has been rightly noticed that: ‘[in] the developing explanatory schemas of postgenomics, the genetic code is no longer thought of as a deep structure that causes and determines, but rather as only one set of relays in complex, ramifying, and nonhierarchical networks,

⁴² Nowlan WJ. 2003. A scarlet letter or a red herring? *Nature* 421:313; Rothenberg KH, Terry SF. 2002. Before it's too late—addressing fear of genetic information. *Science* 297:196–97; Wertz DC. 2002. Genetic discrimination—an overblown fear? *Nat. Rev. Genet.* 3:496.

⁴³ Bombard Y, Penziner E, Suchowersky O, Guttman M, Paulsen JS, et al. 2008. Engagement with genetic discrimination: concerns and experiences in the context of Huntington disease. *Eur. J. Hum. Genet.* 16:279–89
Bombard Y, Veenstra G, Friedman JM, Creighton S, Paulsen JS, et al. 2009. Perceptions of genetic discrimination among people at risk for Huntington's disease: a cross sectional survey. *BMJ* 338:b2175; Taylor SD, Treloar S, Barlow-Stewart K, Stranger M, Otlowski M. 2008. Investigating genetic discrimination in Australia: a large-scale survey of clinical genetics clients. *Clin. Genet.* 74:20–30 ; Thornicroft G, Rose D, Sartorius N. 2007. Stigma: ignorance, prejudice or discrimination? *Br. J. Psychiatry* 190:192–93; Townend D. 2010. Privacy, health insurance and medical research: tensions raised by the European data protection law. *New Genet. Soc.* 29:477–93; M. Otlowski, S. Taylor, Y. Bombard, *Genetic Discrimination: International Perspectives*, *Annu. Rev. Genomics Hum. Genet.* 2012 13:433–54

filiations, and connections.⁴⁴ However, even if we accept that the distinction between innate and acquired characteristics is in fact based on false premises, the technologies developed from and reinforcing these assumptions could still be used in order to control individuals and societies. Whether information is a product of genetic, biological, or environmental factors or a result of complex colleration systems is irrelevant, if an individual perceives it as essential for the development of his or her personality. Hence, the balance between freedom of information and freedom of research on the one hand, and privacy and security of the patient's data on the other, continues to be one of the most important legal problems of new biomedicine.⁴⁵

2.3. Proportionality

The last issue highlights the need for a different approach in debates about public interest. Instead of trying to define what constitutes public interest (it is clear that the promotion and development of science, health care, security, social wellbeing is in the public interest and as the precise understanding of the notion will inevitably change over time defining it more precisely could be counterproductive from a regulatory point of view) more attention should be afforded to the question of *proportionality*. Thus, instead of focusing on the question of what is the legitimate purpose for which data can be used, the effort should be directed towards defining what uses of biomedical data constitute a *necessary* (proportionate) intervention into personal freedom and private life. One will have to choose the least burdensome means of achieving the goal. Framing these issues in terms of proportionality allows identify more easily the uncertainties with regard to a particular project. Although the issue of weighing up different interests remains at the centre of most deliberations about biomedicine and biomedical research, the notion of proportionality is rarely explicitly expressed outside the human rights discourse at the European level. This is because the concept of proportionality has found its way to English law only very recently through the application of EU law. Nevertheless, it is becoming increasingly popular among the judiciary as it provides a more useful tool to assess conflicts of rights (interests). When examining whether an act (or an action , e.g. of processing biomedical data) is proportionate one will take into account the potential harm to the individual rights and freedoms. Therefore, taken from this perspective a use of data should be (legally) irrelevant, if they are unaware of it

⁴⁴ N. Rose, *The Politics of Life Itself. Biomedicine, Power, and Subjectivity in the Twenty-First Century*, Princeton University Press 2007, 16.

⁴⁵ *Ibid.*, 16.

provided that appropriate mechanisms are in place guaranteeing that such use will indeed *never* affect them.

2.4. Property

The issue of ownership over different data has been long present in legal debates about transfer (including commercial secrets), intellectual property rights, and personal data protection (in particular DNA and genetic data). There are powerful arguments in favour of using property regimes to regulate the use of data. Ownership in English law is usually conceptualized as a bundle of rights which entail: protection from interference, free (and usually unlimited) use and control over property, and the right to dispose of it freely. This means that the owner can transfer the legal title over property to another person and as a result lose all the entitlements and links connecting him to the property. In the context of biomedical data it would mean that the owner has absolute (peremptory and possessory) rights over the information until he or she decides to transfer the legal title to another natural or legal person. There is also the legal notion of co-ownership which allows for shared property over things (usually expressed in terms of percentage). Property rights are abstract and absolute and they are effective *erga omnes*. Consequently, property rights offer transparency and certainty in the legal sphere. The introduction of ownership in the field of biomedical data also opens the possibility of their commercialization (although it is also conceivable to exclude a chattel from the market and make something a *res extra commercium*). Such conceptualisation might be appealing as a means of empowerment of the individual: a) strengthening his/her protection (peremptory actions are much stronger than those based on data protection laws), b) allowing more control over personal data (no action can be undertaken with regard to property without the owner's agreement), c) the owner is entitled to all benefits resulting from the property.

However, there are certain powerful arguments against a property regime with regard to biomedical information. They are twofold. On the one hand, it would be very difficult to accept that once the transfer of property rights over data is concluded, all connection to the data cease to exist. Unlike other types of property (or information), biomedical data (unless anonymised) will always remain linked to the person(s) to which they relate or from which they have been collected (this is especially true for genomic information). More importantly, it is difficult to imagine co-ownership over biomedical data, although clearly some

biomedical data extend over families, generations and/or ethnic groups. It is almost impossible to imagine how to express the share over data in terms of property rights and what types of disputes would emerge should such a regime be established. Furthermore, unlike chattels (biological samples, DNA, etc...) the immaterial character of the information might also create operational problems. As information can be copied an indefinite number of times and different copies can be stored in different places simultaneously, it makes some issues concerning possessory rights and liability almost impossible to resolve. Information can of course be subject to intellectual property rights, but that regime is based on a different rationale and serves a different purpose. There is of course the possibility to establish rules which would allow the data subject to receive financial reward?compensation? or other benefits stemming from the research using one's data, but this could be achieved without a recourse to ownership (in the legal sense). Last, but not least, introducing a property regime would make it extremely difficult to negotiate any transnational exchange of biomedical data, as the legal framework of property rights – belonging to the field of private law - varies dramatically across the world (even in the European Union private law escapes harmonization). Using property rights as a starting point could impede research even if data were to remain *rei extra commercium*.

Consultation question 3:

What is the impact of developments in data science and information technology?

Possible aspects to consider:

- To what extent and in what ways has the availability of biomedical data and new techniques for analysing them affected the way in which biomedical research is designed and funded? Is there any evidence that these factors have affected (or are likely to affect) research priorities?
- What are the main interests and incentives driving advances in data science and technology that can be applied to biomedical data? What are the main barriers to development and innovation?
- Does 'big data' need a more precise definition or is it a useful concept in the life sciences even if loosely defined? Has enthusiasm for 'big data' led to over-inflated expectations on the part of governments, researchers and/or the general public?

- What are the significant developments in the linking or use of biomedical data, including any we have not mentioned, to which we should pay attention in our deliberations?

Consultation question 4:

What are the opportunities for, and the impacts of, use of linked biomedical data in research?

Possible aspects to consider:

- What are the hopes and expectations associated with data use for biomedical, public health and life sciences research? What are the main concerns or fears?
- To what extent do the kinds of collaborations required for data-driven research (e.g. international or multi-centre collaborations) generate new ethical and social issues and questions to those in other forms of research?
- Should researchers be required to allow others to access data they have collected for further research?
- What sorts of concerns are raised when research is carried out by a commercial firm?

4. As mentioned earlier, research using linked biomedical data has allowed researchers to conduct hypothesis-free studies, which is proving to be much more comprehensive and effective (e.g. unprecedented progress in the field of Alzheimer's research).

If we consider medical research and the development of preventive personalized medicine to be in the public interest, a logical consequence would be to require researchers to allow others to access data they have collected for further research. However, this would require fundamental changes in the principles governing scientific research, in particular intellectual property rights.

Research carried out by commercial firms raises concerns. However, they are not specific to projects using biomedical data. First of all, a for-profit entity operating in a highly competitive environment will be focused on maximizing profit and cost-effectiveness. However, this does not have to be restricted to commercial firms. There is evidence that in India the state acts as a market agent setting up premises of biotech firms in areas of high

unemployment, thus making the Indian population available as experimental subjects to Western corporate interests and in turn perpetuating postcolonial inequities.⁴⁶ Second, the old problem of expensive treatments excluding poor populations from access to effective medical treatment has not been resolved and it seems that transnational research using large-scale data bases might exacerbate these problems. biobanking across borders

Consultation question 5:

What are the opportunities for, and the impacts of, data linking in medical practice?

Possible aspects to consider:

- What are the main hopes and expectations for medical practice associated with increased use of linked electronic data? What are the main concerns or fears?
- What can be said about public expectations about the use of health care data, in terms of appropriate use, information and control? To what extent would members of the public expect health care data to be shared with other agencies or bodies?
- Is there potential for privacy controls to hide secrets, such as abuse, or to disadvantage people in unintended ways (by preventing best treatment, perhaps)?
- Are there particular issues raised by 'risk-profiling' where individuals at high-risk (e.g. of type 2 diabetes) are identified and approached for specific interventions? What might make the difference between this being intrusive and it being supportive?
- What are the implications of episodes of treatment across different care providers being used routinely as research data? How might this affect the ethical basis of the doctor-patient relationship?
- To what extent does the possibility that [biomedical data](#) can contribute to a research base to advance the effective treatment of others create a moral obligation to allow them to be used in this way? What might limit this obligation? How should we regard (and provide for) those who refuse to allow their data to be used?

⁴⁶ K. S. Rajan, Two Tales of Genomics: Capital, Epistemology, and Global Constitutions of the Biomedical Subject, 193-216.

5. There are two main points to be made here. First is that according to the current legal regulation of personal data, medical data can only be processed if it is necessary in the context of health care, as long as appropriate rules concerning confidentiality are observed. This rule has been well established at the national and supranational level (ECHR jurisprudence, EU Directive 44/96 on personal data protection, Data Protection Act 1998, Social and Health Care Act 2012). Thus, patients have a legitimate expectation to believe their data will not be used by outside the health care system, unless it is necessary for the protection of public safety (W v Edgell). Consequently, as the right to privacy is not an absolute right and has inherent limitation clauses allowing for some scope of flexibility, it is difficult to see how the protection of privacy would undermine the possibility of receiving best treatment. The fear that has been expressed, however, is related to the recent shift towards privatization of health care undertaken by the coalition government. Anecdotal evidence suggests that doctors are less likely to encourage their patients to participate in research using biomedical data in fear of future privatization of health care which might compromise the standards of personal data protection.

A second point relates to data sharing between health care providers and research projects. It is important to remember that the rules governing medical practice (health care) are different from those regulating the use of data for medical research. Medical research consists of a patchwork of common law and statutory principles, different for persons with and without mental capacity to consent, children and adults. Should data sharing be promoted, an alignment of those two sets of regulations would have to be carefully considered.

Consultation question 6:

What are the opportunities for, and the impacts of, using biomedical data outside biomedical research and health care?

Possible aspects to consider:

- What are the main hopes and expectations associated with the wider use of biomedical data (outside biomedical research and clinical practice)? What are the main concerns or fears?
- What factors are relevant to determining the legitimate scope of further uses of biomedical data? For example, should it be restricted to a 'compatible purpose' (and, if so,

how might this be defined)? To uses that are in the 'public interest'? To use only by public authorities (and those providing public services under contract)? To non-commercial or non-profit uses/users?

- What are the ethical implications of using [predictive analytic](#) tools with biomedical data outside health care and research (e.g. in recruitment or workforce management)?
- Would the ability of individuals to maintain direct control over the use of data about them be likely to affect the range of further uses to which they would allow the data to be put?
- Should individuals be able to profit from the use of their biomedical data (e.g. by selling access to the data to commercial companies)?

6. The concept of *public interest* enjoys an uneasy relationship with notions of privacy because public interest is often held out as a justification for interference with privacy rights.⁴⁷ In the context of data protection law⁴⁸ processing is allowed, without a person's consent, if it is necessary for public health purposes and 'for reasons of substantial public interest', including scientific research, as long as the confidentiality principle is respected.⁴⁹ However, the nature and scope of such public interest remains illusory. Respect for public interest can be understood simply as avoidance of harm to others or as promotion of socially beneficial ends – two interpretations which 'cannot always co-exist peacefully'⁵⁰. The contradiction is visible if we perceive as public interest not only medical research, but also the protection of individuals' rights to privacy and confidentiality. Thus, again, the balancing between two different public interests (privacy and medical research) needs to be done on a case-by-case basis.

David Beyleveld has suggested a 'co-operative model' of interaction between privacy values and medical research values. In this model values of medical research, including its

⁴⁷ *Z. v. Finland*, Application No. 22009/93, (1997) 25 EHRR 371. The criterion of necessity has been interpreted by the Strasbourg organs as being satisfied when the interference addresses 'a pressing social need', in: *Leander v Sweden*, Application No. 9248/81, (1987) 9 EHRR 433.

⁴⁸ Data Protection Directive 95/46/EC (OJ L 281 , 23/11/1995 P. 0031 – 0050) is used here as the European standard of data protection. Despite initial problems with its implementation, it has contributed to a substantial harmonization of data protection law across Europe.

⁴⁹ Article 6 para. 1 (a) and article 8 para. 3 and 4 of in conj. with para. 34 Preamble of the Data Protection Directive 95/46/EC.

⁵⁰ M Häyry and T Takala, "American principles, European values and the mezzanine rules of ethical genetic databanking", in M Häyry, R Chadwick, V Árnason and G Árnason (eds) *The Ethics and Governance of Human Genetic Databases* (Cambridge University Press, 2007), 21.

aim to improve quality of life and increase choices, are incorporated within a broad concept of private life: respect for private life facilitates trust, which is absolutely crucial for research.⁵¹ This construct is very interesting, although the attempt to fit the freedom of research into the framework of the right to private life can be rather arduous. Laurie et al. have developed another way to reconcile individual and common (public) interests, suggesting that ‘participants in a biobank could have a say in the use of the resource and could help to define and refine what it means to use it “in the public interest”. This could include input on where to set a level of adequate privacy protection and/or where compromises on privacy might be reached.’⁵² Although not expressly stated, such a solution seems to comply with the idea of the right to personality. However, it leaves unsolved the problem of understanding of genetic knowledge by research participants.

Consultation question 7:

What legal and governance mechanisms might support the ethical linking and use of biomedical data?

Possible aspects to consider:

- What ethical principles should inform the governance of [biomedical data](#)? For example, should the principle of ‘respect for persons’ be given primacy here? How might this relate to principles such as solidarity and tolerance?
- Does the use of linked biomedical data require distinctive governance arrangements compared to the use of other personal data?
- Are the current principles of consent – including the principle that consent can be withdrawn – still ‘fit for purpose’ in relation to the linking of biomedical data?
- What level of continuing involvement is it reasonable to expect individuals to have in how their data are used after they have been collected?
- Should there be an opt-in or an opt-out system for people to decide whether to allow their personal medical data to be used for public benefit?

⁵¹ D. Beylveid, “Data Protection and Genetics: Medical Research and the Public Good”, 18 *King’s Law Journal* (2007), 275–289.

⁵² Nuffield Council on Bioethics (Barbara Prainsack and Alena Buyx), *Solidarity Reflections on an emerging concept in bioethics*, November 2011; G.Laurie et al., “Managing access to biobanks: How can we reconcile individual privacy and public interests in genetic research?”, *Medical Law International* 10(4) 2010.

- Under what conditions ought individuals to be content to delegate authorisation of the use of health and biological data about them?
- What role should public engagement and democratic processes play in the determination of governance measures? In what circumstances, if any, might the outcome of democratic procedures mandate overriding individual interests?
- What inconsistencies exist in current ethical guidance and governance structures relating to biomedical data?
- What examples are there of innovative initiatives that promote privacy while encouraging participation?

7.1. Main principles

The main concerns with regard to the use of biomedical data are still issues related to discrimination, stigmatization, and social exclusion. Thus any governance framework concerning the use of biomedical data should be comprehensive (covering areas outside research and health care), and should be based on principles of non-discrimination and social justice (inclusion). It is submitted here – perhaps controversially – that research carried out with the use of data will never be as intrusive as other forms of medical research. Therefore, as long as individuals and groups are protected from negative consequences leading to social stigmatization, exclusion from employment or insurance based on predictive information – the use of biomedical data should be facilitated. Respect for persons and private life are certainly important principles that should be taken into account when designing new forms of regulation. However, what is also important to highlight is that there are instances where entities using personal data for research (e.g. pharmaceutical companies) use protection of research subjects and their privacy as a shield against external (ethico-legal) scrutiny and control. Yet, little attention is usually afforded to the principle of transparency and openness. Therefore, it is equally important that these principles become central to such governance.

7.2. Privacy and the right to personality

Privacy rights are rights protecting the conditions necessary to maintain arenas of valuable personal and social activity.⁵³ The right to privacy derives its weight from its capacity to foster the conditions of a wide range of other aspects of human flourishing. Fostering a degree of privacy is important as it helps to create the conditions in which one can advance interests which are of more fundamental value. It is a condition of self-fulfilment. In *Botta v Italy* the Court recognised that ‘the guarantee afforded by Article 8 of the ECHR is primarily intended to ensure the development, without outside interference, of the personality of each individual in his relations with other human beings.’⁵⁴ At its core privacy represents only one aspect of personality. However, in the Court’s view a right to personal development is protected by Art. 8 only ‘in addition’ to other various aspects of person’s ‘private life’. The progressively extensive interpretation of the latter concept developed by the ECtHR may lead to augmentation of the concept of privacy and eventually a loss of its semantic boundaries.

In the context of (post-)genomics science the difficulties of the protection afforded under the right to private life are evident on various different levels, already discussed above: a) with regard to consent, which is the crucial exonerating factor for interference; b) with regard to public interest, which justifies interference with private life even without consent of the individual; and c) with regard to confidentiality and anonymity, the latter of which according to data protection theory results in the inapplicability of privacy rules altogether.⁵⁵ Therefore, it is claimed here that instead of genetic privacy a broader perspective could be gained by employing the German notion of the right to personality as a new frame of reference. While far from providing ultimate solutions to particular problems, a right to develop one’s personality offers a much wider, multi-level, and flexible conceptual framework that could lead to a more comprehensive and dynamic human rights protection of the individual in the area of genomics and biomedicine in Europe.

The right to personality (*Persönlichkeitsrecht*) is not a new concept. Its origins are to be found in the early 20th century, in the German civil code (*Bürgerliches Gesetzbuch, BGB*) where compensation was guaranteed in case of damage to a person’s life, health or freedom.⁵⁶ However, its full recognition as a constitutional principle came only in the second half of the

⁵³ D. Feldman, “Privacy-related Rights and their Social Value”, in: P. Birks (ed.), *Privacy and Loyalty*, Oxford Clarendon Press. Publication, 1997, 16.

⁵⁴ *Botta v. Italy*, 24 February 1998, Application No. 21439/93. See also: *Burghartz v. Switzerland*, 22 February 1994, § 24, Series A no. 280 B.

⁵⁵ In principle, as long as data remain unidentifiable, they are not seen as ‘personal data’, hence, privacy or data protection laws will not apply.

⁵⁶ § 823 BGB (German Civil Code) (BGBl. I S. 42, 2909; 2003 I S. 738).

20th century, following World War II. First the German Federal Supreme Court (*BGH*)⁵⁷ and then the German Federal Constitutional Court (*BVerfG*)⁵⁸ inferred ‘the general right to personality’ (*Allgemeines Persönlichkeitsrecht*) from § 2 I (freedom of action) in relation to § 1 I (inviolability of human dignity) of the German Constitution (*Grundgesetz* 1949).⁵⁹ At the core of this right are human dignity, individual autonomy, physical inviolability, the free development of a person, and the right to respect for personal privacy as a *conditio sine qua non* for the flourishing of personality.⁶⁰ As such the protection afforded by the right to personality covers more dimensions of human life than the right to privacy. In the personalist universe envisioned by the German Constitutional Court the human person is much more than a biological or physiological organism; it is a ‘spiritual-moral being’.⁶¹ This concept seems to realise Amartya Sen’s vision, in which a person consists of two aspects: the agency aspect and the well-being aspect – and cannot be reduced to just one dimension nor can these two aspects be forced to coincide.⁶² An analogy can be drawn between the image of a person stemming from the right to personality and the holistic approach advocated by the developmental systems theory. The Constitutional Court promotes an ‘inter-relational image’ of a person. In the landmark *Life Imprisonment* case (1977)⁶³, the Constitutional Court stated: ‘The freedom [to act] (...) is not that of an isolated and self-regarding individual, but rather [that] of a person related to and bound by the community. In the light of this community-boundedness it cannot be “in principle unlimited”. The individual must allow those limits on his freedom of action that the legislature deems necessary in the interest of the community’s social life; yet the autonomy of the individual has to be protected. This means that [the state] must regard every individual within society with equal worth.’⁶⁴

Citizens are members of and bound to a society and thus all persons are required to accept certain restrictions on their privacy on behalf of an overriding public interest tempered, of course, by respect for inviolable sphere of personality and by strict compliance with the

⁵⁷ BGH, 25.05.1954, BGHZ 13, 339.

⁵⁸ BVerfG, 15.01.1958, BVerfGE 7, 198.

⁵⁹ The Basic Law for the Federal Republic of Germany, 23 May 1949, last amnd. 21 July 2010 (BGBl. S. 1, BGBl. I S. 944).

⁶⁰ Zweigert and Koetz, *An introduction to comparative law* (Oxford, Clarendon Press, 1998), pp. 686—693.

⁶¹ D.P.Kommers, *The Constitutional Jurisprudence of the Federal Republic of Germany*, Duke University Press: Durham and London 1997, 323.

⁶² A.Sen, *Inequality re-examined*, Oxford University Press 1995, 56.

⁶³ The Federal Constitutional Court considered the question of whether statutes which allow for life imprisonment in certain extreme cases of homicide are compatible with the inviolability of human dignity. See: BVerfG, 21.06.1977, 45 BVerfGE 187.

⁶⁴ BVerfG, 21.06.1977, 45 BVerfGE 187.

principle of proportionality.⁶⁵ At the same time, although the right to personal freedom may be limited by an act of parliament, parliament's freedom to introduce legislation is limited by the constitution in a number of ways. Interventions are only possible to further a general legal interest (*Rechtsgut*) of constitutional status. In the *Life Imprisonment* case the German Court emphasised that '[i]n exercising its powers the legislature must take account of both the inviolability of human dignity (§ 1 (1)), which is the highest value of the constitutional order, as well as constitutional principles such as equality (§ 3 (1)), the rule of law, and the social state (§ 20 (1)).'⁶⁶ It follows that, at least conceptually, the right to personality as it appears in the German Basic Law, provides a more comprehensive, but also more context-specific protection of the individual than the protection based solely on privacy and autonomy. It leaves room for restrictions in the name of overriding public interests with appropriate legal justification. The context in which the individual develops his or her personality is of paramount importance to the whole concept.

Although the right to personality is not an objective value like the principle of human dignity, it constitutes: a) an objective rule requiring justification for all interventions, b) a free-standing cause for action, and crucially c) a source for other rights that enable human flourishing.⁶⁷ Due to this 'gap-closing function', the right to personality did not leave the plaintiffs in the case unprotected in the event of the inapplicability of the conventional fundamental rights in the German Constitution.⁶⁸ Although the content of the *Persönlichkeitsrecht* has never been fully defined, the courts have sought a way of upholding different rights essential for the development of one's personality.⁶⁹ Sub-rights, developed in the course of time as a response to social changes, include the right to one's own image and word, the right to know one's biological parents, and the right to sex change.

Very recently, the Court has used the 'gap-closing function' of the right to personality once again, to create a new 'basic right to confidentiality and integrity of information-technology systems', which precludes secret on-line searches of personal computers by government

⁶⁵ D.P.Kommers, *The Constitutional Jurisprudence of the Federal Republic of Germany*, Duke University Press: Durham and London 1997, 317.

⁶⁶ BVerfG, 21.06.1977, 45 BVerfGE 187.

⁶⁷ Maunz and Dürig (eds), *Grundgesetz. Kommentar* München, C.H. Beck, 2004, Art. 2.

⁶⁸ G. Hornung, Ch. Schnabel, "Data protection in Germany II: Recent decisions on online searching of computers, automatic number plate recognition and data retention." 25 *Computer Law & Security Report* 2 (2009), 115-122.

⁶⁹ BGH, 2.04.1975, 24, 72, in: W. van Gerven et al. (ed), *Cases, Materials and Texts on National, Supranational and International Tort Law*, Hart Publishing: Oxford, Portland Oregon 2000, 143.

agencies.⁷⁰ The information stored on personal devices or spaces accessible from the internet is worthy of protection insofar users' private accounts 'contain personal data of the affected person in a scope and multiplicity such that access to the system makes it possible to get insight into relevant parts of the conduct of life of a person or even gather a meaningful picture of the personality.'⁷¹ It could be argued that, if linked with other personal data, biological data provide insights into relevant parts of person's life. Therefore, regardless of whether this judgment has a bearing on the use of biological information in databases (or even a micro-chip), the right to personality arguably proves to be an open textured concept capable to accommodate to new challenges of technology, science and medicine.

Nearly 30 years earlier, in a famous case of the national census (*Volkszählungsurteil* 1983), the Constitutional Court had observed that 'the technical means of storing highly personalized information about particular persons today are practically unlimited, and [information] can be retrieved in a matter of seconds (...), irrespective of distance'. Therefore, it was held necessary to recognise the 'right to control whether and to what extent the information about [person's] life is used'; the right to informational self-determination (*Recht auf informationelle Selbstbestimmung*).⁷² This right puts the individual in the position to, in principle, decide for him/herself which personal information is to be disclosed in his/her social environment. Based on the ideas of purpose specification and proportionality, the German Constitutional Court developed an extensive prohibition of data retention. The collection of non-anonymised data for unspecified purposes or purposes to be specified later would be a violation of these principles. An exception can only be made for anonymised data which is collected for means of statistics.⁷³ The right to self-determination in the context of biomedicine was recently spelled out as a 'right to bio-informational and bio-material self-determination'.⁷⁴

If interference with their rights is deemed necessary, citizens must be allowed the means to assess the risks for their personality connected with a processing of their personal data.⁷⁵ The

⁷⁰ Interference with *Grundrecht auf Gewährleistung der Vertraulichkeit und Integrität informationstechnischer Systeme* is possible only if there are 'factual indications for a concrete danger' in a specific case for the life, body and freedom of persons or for the foundations of the state or the existence of humans. Such interventions require judicial approval. See: BVerfG, 27.02.2008, 1 BvR 370/07.

⁷¹ This includes primarily laptops, PDAs and mobile phones, but there is certainly a scope for encompassing other information systems. See: BVerfG, 27.02.2008, 1 BvR 370/07.

⁷² BVerfG, 15.12.1983, 65 BVerfGE, 1.

⁷³ BVerfG, 15.12.1983, 65 BVerfGE, 1

⁷⁴ Ch. Halász, *Das Recht auf bio-materielle Selbstbestimmung*, Springer: Berlin 2003.

⁷⁵ P. Kunig, in: I. von Münch / P. Kunig (eds), *Grundgesetz-Kommentar* (5th ed.), Beck 2000, Art. 2 para. 38.

legislature is thus responsible for adopting institutional and procedural measures designed to safeguard the individual from any infringement of this right to personality.⁷⁶ It follows that, the legislature is required to specify the purposes and conditions of all data-gathering process so that the citizen may clearly know what information is being collected and why. Such legal authorization must adhere to the rule of law, the principle of proportionality, and be clearly framed so as not to be unconstitutionally vague or uncertain. As such, the informational self-determination guarantees *a priori* (pre-emptive), rather than *a posteriori* (subsequent) protection to the individual.

It seems, therefore, that informational self-determination and data protection have two corresponding effects.⁷⁷ Data protection is a precondition for citizens' participation in the democratic state. The right to informational self-determination guarantees a free and democratic communication order.⁷⁸ While it is possible to justify interferences in the right to informational self-determination if a consideration shows that the public interest outweighs the legitimate interests of the individual, the basic idea is always the same: the data subject is to maintain control of his/her own data. The right to informational self-determination thus combines two aspects of person's life in relation to data use: privacy and autonomy. However, what makes it conceptually sounder than the right to private life and personal data protection taken together is the fact that it is directly and inextricably linked with the protection of human dignity.

The right to personality in the context of genomics and post-genomics

Such conceptualisation of the individual in relation to his/her personal information gives some weight to the argument for the regulation of biological data in the context of genomic and post-genomic research and clinical practice. The right to informational self-determination imposes an obligation on the state to organize the collection, storage and transmission of information in a way that respects the individual's autonomy. In the context of health care databases such understanding leads to a requirement to secure a wide and comprehensive organisational and regulatory framework that should be activated before a data collection is

⁷⁶ BVerfG, 15.12.1983, 65 BVerfGE, 1.

⁷⁷ S. Simitis, "Datenschutz – Rückschritt oder Neubeginn?", *Neue Juristische Wochenschrift* (1998), 2473-2475.

⁷⁸ G. Hornung, Ch. Schnabel, "Data protection in Germany I: The population census decision and the right to informational self-determination", 25 *Computer Law & Security Report* 1 (2009), 84-88, 87; available via: <http://dx.doi.org/10.1016/j.clsr.2008.11.002>.

established. This was reflected in the Opinion on ‘Human biobanks for research’ issued in 2010 by the German Ethics Council.⁷⁹ The opinion generally favoured a liberal interpretation of the right to personality and informational self-determination, and it used these rights to derive some innovative ideas about a five-pillar concept for biobank legislation. The Council suggested that the central element of any regulatory proposal must be the right to self-determination (bodily as well as informational).

The first and most important pillar of this concept is the introduction of ‘biobank secrecy’, mirroring medical confidentiality. This should restrict the processing and transmission of samples and related data for the duration of their existence to the purposes of scientific research and guarantee that they are inaccessible to all non-research third-parties. At the same time, confidentiality, as reflected in the right to personality would also be subject to limitations with regard to the constitutionally guaranteed freedom of research⁸⁰ according to the proportionality principle. The second provides for broad consent as a possibility open to donors. As the third pillar, the Ethics Council recommends involving ethics commissions, firstly, to provide for cases where personal samples and data are to be used or there is an intention to recontact donors, and secondly in order to periodically evaluate the activities of biobanks which are not restricted in subject and duration. The fourth pillar relates to quality assurance. Donors’ rights should be protected by appropriate organisational structures and procedures and a system evaluation of all biobanks not narrowly restricted in subject and duration. As the fifth pillar of its legislative concept, the Ethics Council calls for a number of measures to guarantee the transparency of the goals and procedures of a biobank. These include in particular complete documentation and regular publication of the activities of the biobank, and setting up a publicly accessible biobank register.⁸¹

Consequently, what could be inferred from the report was that biobanks for research can only be justified if policy safeguards are introduced as a *conditio sine qua non* for their establishment and maintenance. This requirement stems from the fact that the right to informational self-determination extends the protection of privacy ‘by already making it start at level of endangerment of the personality. Such endangerments=situations can already arise

⁷⁹ German Ethics Council, *Opinion: Human biobanks for research*, Berlin 2010, available via: http://www.ethikrat.org/files/der_opinion_human-biobanks.pdf, accessed on 20.11.2010. This opinion has built upon the former National Ethics Council’s *Opinion: Biobanks for research* issued in 2004, available via: http://www.ethikrat.org/english/publications/Opinion_Biobanks-for-research.pdf, accessed on 09.09.2010.

⁸⁰ § 5 (3) Basic Law for the Federal Republic of Germany, 23 May 1949, last amnd. 21 July 2010 (BGBl. S. 1, BGBl. I S. 944).

⁸¹ German Ethics Council 2010, 47-53.

in the run-up to concrete threats to specific legal interests, in particular if personal information can be used and linked in a manner which the person concerned can neither detect nor prevent.’⁸² Generation of large volumes of data that give rise to particular risk of linkage and inference of personal profiles is to be accompanied by the statutory prohibition of genetic discrimination set out by the German Human Genetic Examination Act⁸³. Any national endeavour would require federal statutory action.⁸⁴ This conclusion can also be derived from the Constitutional Court’s deliberations on personality profiles. Such profiles, created by means of gathering information which goes beyond that which can be obtained from the original data, may pose a threat to the individual’s right to informational self-determination. Through the combination and the linking of seemingly harmless information, new and maybe even sensitive data can be *generated*, which the individual has never actually ‘disclosed’.⁸⁵ In the *Mikrozensus* decision (1969) the German Constitutional Court came to the conclusion that the collection of all official data with the intention of creating a complete personality profile ‘even in the anonymity provided by a statistical census’ would violate the guarantee to have one’s dignity recognised, ‘since the individual would be treated as an object accessible to an inventory in every way.’⁸⁶

However, it would be incorrect to say that the right to personality always provides for a more stringent protection of the individual than in the case of privacy. Rather, the level of protection will always depend on the extent to which a use of biological information affects the right to personality and informational self-determination. If it is found that in a specific case such use, whether in research or clinical practice, really does affect the personal interest of the data subject, the use will be unlawful and can be rendered lawful only if the consent of the holder of the right is obtained. Here, however, the questions raised in privacy discussions re-emerge, in particular questions relating to the need for specific consent; time limits for consent; and the information that should be made available to donors to allow them to give

⁸² BVerfG, 27.02.2008, 1 BvR 370/07, 312.

⁸³ § 4 *Gesetz über genetische Untersuchungen bei Menschen (Gendiagnostikgesetz - GenDG)*, 31.07.2009 BGBl. I S. 2529, 3672.

⁸⁴ *Prima facie* such an interpretation is the reason why biobanks in Germany are predominantly local. However, the main reason is political, for public opinion, especially in former Eastern Germany is, due to the 20th century German history⁸⁴, extremely sceptical towards genetic research and any forms of potential surveillance. The local framing of biobanking is misleading in that although the recruitment takes place locally, the use of data and samples is taking place at the national and even international level. See: I. Schneider, “This is not a national biobank...The politics of local biobanks in Germany”, in: H. Gottweis, A. Petersen (ed.), *Biobanks: governance in comparative perspective*, Routledge 2008, 88-108, 92-93.

⁸⁵ G. Hornung, Ch. Schnabel, “Data protection in Germany I: The population census decision and the right to informational self-determination”, 25 *Computer Law & Security Report* 1 (2009), 84-88, 88.

⁸⁶ BVerfG, 16.07.1969, 27 BverfGE 1.

valid consent. The framework for the right to personality does not provide any instructions as to how to answer these dilemmas. Nevertheless, it has been argued that if on the other hand, personal interests are deemed unaffected then the researcher does not need to obtain consent from the right holder.⁸⁷ His actions will only be unlawful if and to the extent he does violate ‘the general right to personality’.

The scope of the *Persönlichkeitsrecht* may vary considerably depending on the configuration of circumstances. As it constantly tends to conflict with the rights of others, it is subject to continuous balancing exercise. In this respect, it reveals great similarities to the right to respect for one’s privacy. In fact, it too has been criticised as too broad and ill-defined.⁸⁸ The ‘ill-defined requirement for “comprehensive balancing of interest” determining whether “the general right to personality” has been violated’ leads to many uncertainties.⁸⁹ It requires the legislator to find a balance between two poles: first, the nature and intensity of the interferences with basic rights, and second, the importance of the value or interest to be protected by the interfering measure.⁹⁰ After all, the general right to personality is a constitutional right, subject to the same balancing processes as other basic rights, including the right to private life. The great difficulty that they all face and that requires special attention is not the vagueness of the notion of public good, but the definition and practical implementation of the principle of proportionality (already mentioned above).

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⁸⁷ J. Taupitz, “Biobanks for research: The German Ethics Council’s Opinion”, in: M. Steinmann, P. Sýkora, U. Wiesing (ed.), *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, Ashgate 2009, 282-296.

⁸⁸ W. van Gerven et al. (eds), *Cases, Materials and Texts on National, Supranational and International Tort Law*, Hart Publishing: Oxford, Portland Oregon 2000, 144.

⁸⁹ J. Taupitz, “Biobanks for research: The German Ethics Council’s Opinion”, in: M. Steinmann, P. Sýkora, U. Wiesing (ed.), *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, Ashgate 2009, 282-296, 286.

⁹⁰ BVerfG, 11.3.2008 - 1 BvR 2074/05 and 1 BvR 1254/07, para. 169, in: G. Hornung, Ch. Schnabel, Data protection in Germany II: Recent decisions on onlinesearching of computers, automatic number plate recognition and data retention. 25 *Computer Law & Security Report 2* (2009), 115-122.