Informational Self Determination, Right to Data Portability and Consent in Biobank Research: Is Research Possible Without Privacy Data Invasion?

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Biobanking functions within the Data Protection Regulation and EU legislation. Evaluation of data portability and informational self-determination and its impacts on the future of biobanking will be covered in the scope of the thesis. With all the discrepancies on consent and its evolution on sensitive data, there will be an evaluation of types of consent out there and their applicability and efficiency in the real sphere of biobanking. The target audience for the thesis are researchers, medical research professionals, and individuals in need of guidance for biobanking. The research is theoretical observed through EU legislation, national legislation and case studies. Recommendations from the study include strict supervision implementation when partnering with for profit companies or third parties on research projects, particularly being careful when a partnership between private and public sectors is initiated. The best suggestion in solving this problem is harmonization of the rights on storing and handling sensitive data. There should be a uniform rule on how private companies shall behave with such data. Adequate consent rights should be implemented with sensitive data. Lastly, there should be limitations or restrictions on compiling and using sensitive biological data.

Keywords: biobank, ethics, consent, data protection

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http://www.eu-patient.eu/globalassets/policy/data-protection/data-protection-guide-for-patients-organisations.pdf

List of Abbreviations

ABCD Amsterdam-Born Children and Their Development Study
CHRB Convention on Human Rights and Biomedicine
CIOMS- The Council for International Organizations of Medical Sciences
DNA- Deoxyribonucleic acid
EC- European Comission
EU- European Union
FIPP- Fair Information Practice Principles
GDPR- General Data Protection Regulation
HBGRD- The OECD Guidelines on Human Biobanks and Genetic Research Databases
HRA The Health Research Act
MS- Member State
RECs- Research Ethics Committees
US- The United States
USC- United States Code
UK- The United Kingdom

List of Legislation

EC Directive 95/46/EC
General Data Protection Regulation EU 2016/679
Declaration of Helsinki 1964
The Health Research Act 2008
Nuremburg Code, BMJ 1996
Convention on human rights and biomedicine, Council of Europe, 1997
Commission Recommendation C (2008) 1329
Article 29 Working Party Guidelines Regulation 2016/679
EC Directive 98/44/EC
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I Introduction

Biobanks have become a popular means to do research and collect data on subjects through genomic research. They have become viewed as research organizations- collecting data and samples from research subjects and making this material available, on application, to researchers. The aim of biobanks is to collect as much data as possible with as few limitations as possible. Many biobanks often do not even specify the type of research the materials will be used for.

This can be problematic as it is only logical that in order to conduct medical research consent must be attained before conducting research on sensitive data.

As biobanks process 'personal data', European data protection law applies in their day-to-day operations. Despite the clear evidence that data protection law applies, there remains uncertainty about the exact application of the General Data Protection Regulation, hereinafter, GDPR. There are questions if open consent is legitimate is one such uncertainty. On top of this there is a wide range of opinions on what types of consent are applicable in the use of sensitive data. In addition to this, the GDPR requires that any consent be 'specific' and 'informed'. This could pose a problem for biobanks operating with open consent as they cannot meet these requirements.

Processing of personal data in biobank-based research involves sensitive data, such as health and genetic information, socio-demographic data, lifestyle and behavioral data, the Regulation provides requirements on regulation of such data. Additionally, principles for fair processing are addressed in the Regulation stipulating that data protection supervisory authorities should provide oversight and supervisory roles. [1]

With all this in mind, there is a clear lack of harmonization in the EU with regard to data protection in the biobanking industry. There are issues concerning cross-border exchange of

[1] Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research. 2013. Biobanks for Europe: A Challenge for Governance. Directorate-General for Research and Innovation. http://ec.europa.eu/research/swafs/pdf/pub_archive/biobanks-for-europe_en.pdf. Accessed 28.05.2018

personal data and sample transfers.[2] In addition to this, there are issues with data security and confidentiality concerns with the exchange of sensitive patient data. [3] The GDPR is extremely relevant to biobanking and needs to be evaluated in understanding how to protect sensitive information from being breached by third parties.

This thesis will examine how biobanking functions within the General Data Protection Regulation and EU legislation. There will be an evaluation of data portability and informational self-determination and its impacts on the future of biobanking. With all the discrepancies on consent and its evolution on sensitive data, there will be an evaluation of types of consent out there and their applicability and efficiency in the real sphere of biobanking. With this there will be an evaluation of case law and how, if at all, patients can manage to keep their privacy and personal data from the hands of third parties through the process of biobanking.

II Informational Self Determination

2.1 Right to data portability and informational self determination

The right to data portability has been a hot topic with regard to privacy recently as it has been included in legislation. Data portability allows an individual to get their data for their personal use from different services or databases storing their data. This allows them to move, copy, or transfer data in a safe secure way without compromising usability.

The right to data portability gives an individual the right to receive personal data through machine-readable format for personal use or move it to another provider if they wish to do so by requesting a data controller to move the data directly to another controller of choice. According to the Open Data Handbook, machine-readable data is considered to be any data in a data format that can be automatically read and processed by a computer. This is lawful only when consent is given or for the purpose of performing a contractual obligation.

[2] Goebel JW, Pickardt T, Bedau M, Fuchs M et.al. Legal and ethical consequences of international biobanking from a national perspective: the German BMB-EU Coop project. European Journal of Human Genetics, 2010, Vol. 18, No. 5, pp. 522-525

[3] Schwarz E, Leweke FM, Bahn S, Liò P. Clinical bioinformatics for complex disorders: a schizophrenia case study. BMC Bioinformatics. 2009, Vol. 10 Suppl 12, pp. S6.

The right to data portability is outlined in article 20 of the General Data Protection Regulation (GDPR). Article 20(2) states "In exercising his or her right to data portability pursuant to paragraph 1, the data subject shall have the right to have the personal data transmitted directly from one controller to another, where technically feasible." Patients contributing their samples for research have gained more rights against the controllers and processors of their data from the new GDPR. These rights include the right to consent, to information, to access, to rectification, to erasure, to restrict processing, to data portability and to object. However, some of these rights may be subject to limitations for scientific research purposes in certain instances.

For our purposes it is important to note that the right to data portability only applied to personal data. Therefore, this leads to the idea that data portability does not apply to anonymous data.[4] Yet, pseudonymous data that can clearly be linked to a specific individual is still within the scope of this right. Notably, the GDPR does not specify how individuals should make data portability requests. Therefore, requests could be made verbally or in writing. A request does not need to include the phrase 'request for data portability' nor does it need any reference to Article 20 of the GDPR.

While the GDPR provides the option of data portability there are exemptions for biobanks from a number of GDPR principles and data subject rights if and when the personal data is being processed for scientific research. For instance, the data storage limitation principle can be revised and personal data can be stored for longer periods so long as they will be administered only for scientific research according to the provisions of article 89(1) of the GDPR and subject to implement technical and organizational measures required by the GDPR. [5] In addition to this, the GDPR allows for further data processing of personal data initially processed for a different for scientific research reasons, if there is a valid legal reason for the initial processing in the EU or Member State, hereinafter MS, laws exist allowing this extended processing.

[4] Article 29 Data Protection Working Party, Guideline on the right to data portability, online: http://ec.europa.eu/information_society/newsroom/image/document/2016-51/wp242_en_40852.pdf
[5] http://www.bbmri-eric.eu/wp-content/uploads/BBMRI-ERIC_FAQs_on_the_GDPR_V2.0.pdf

Informational self-determination is a fundamental element of human dignity but so are the rights to physical wellbeing, and we need the best in research and education if we want to guarantee European values granted to us. The data protection regulation is not very flexible since it was originally conceived before the rampant Internet era. The problem that arises through the process is the protection of personal data and how this can be achieved efficiently. Informational self-determination and how to maintain it also comes into question here.

Informational self determination has German origins when in a well-known German census decision, the German Federal Court stated that informational self determination is a personality right, which ensures the individual the right to control how their personal data is issued and utilized. [6] Informational self determination has evolved but still remains closely linked to Westin's definition of privacy as, "the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extend information about them is communicated to others."[7]

Informational self determination is the ability of an individual to determine the disclosure and the use of their personal data, to control and to determine what others can find out them. In order for an individual to keep control over their data they must be informed about the purpose of processing and the identity of controllers, as well as all the rights that they have to their personal data.[8] Put simply, the right to informational self-determination infers that it cannot function properly without transparency when processing the data.

The concept of transparency can be found in Article 13 of the General Data Protection Regulation. Fair and transparent processing requires that the data subject be informed on the processing of their data, its purpose, how long the data will be stored, the right of access, rectification or erasure and on the right to lodge a complaint. [9] Additionally, Article

[6] German Federal Constitutional Court (BVerfG, 15 December1983). Online: http://www.servat.unibe.ch/dfr/bv065001.html#Rn003
[7] Westin, A. 1967, 'Privacy and Freedom', Bodley Head, London. p. 7
[8] Eva Fialova, Data Portability and informational self-determinaton, Masaryk University Journal of Law and Technology, Vol. 8:1, 2014
[9] Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of

12 of the General Data Protection Regulation stresses that the controller should have concise, transparent, clear and easily accessible policies with regard to processing of personal data and the exercise of data subjects' rights.

Informational self determination can be viewed as a proprietary right to personal data. Data portability is the transfer of an object, taken from one place to another and handed over, in our case the data transfer is the data subjects personal data. Data portability as proposed in the General Data Protection Regulation as two relatively separate rights, the right to obtain a copy from the controller and the right to data transfer.[10] Even though, these rights enhance informational self-determination, they do not guarantee full control over personal data, as there is even differentiation on when the data portability can be extended based on the necessity of the material gathered from the data subject.

Data portability increases informational self-determination of the data subject. Data portability should provide the data subject with control over the personal data.
It is no question that informational self-determination is directly linked with information privacy. The data subject may determine to whom they disclose their personal data if at all. Their decision on this matter should be made freely without any undue influence from a third party for informational self-determination to be preserved. Nonetheless, the right to data portability, provides a means for providers to attract users with even more personalized services. These developments can result in lax rules on privacy protection of informational privacy of the data subjects for various reasons, whether to make profit or to promote research.

2.2 Informational self determination and its effect on medical research

Current developments in the genetic analysis and biobanks present new challenges to the right to informational self determination. Biobanks collect and use samples linking them to data, through this process researchers can gain access to personal characteristics of donors that may previously have been inaccessible to the donors themselves. The data subjects

such data (General Data Protection Regulation), COM(2012) 11 final from 25 January 2012.
[10] Eva Fialova, Data Portability and informational self-determinaton, Masaryk University Journal of Law and Technology, Vol. 8:1, 2014

concerned must give their informed consent. However, as we have seen, biobanks store samples and personal data for future research projects that are not yet specified at the time consent is given.[11] Therefore, donors don't actually know precisely what their samples and data will be used for. For this reason, general consent is often used. With this type of consent, donors consent to their samples and data being used for research in general, thus no specific research projects are specified. This means that data subjects do not have to be informed when a new project uses their samples.

Informational self determination is key in medical research and the participants can implement their self determination right with regard to the research taking place. Informational self determination of patients applies to the purpose for which their personal data will be used. This is done through informed consent by a patient when they allow their biomedical data or treatments be used for a specific research or a general research.[12] However, in some cases like routine data used in scientific analysis, consent of the person cannot be obtained. When this occurs, the freedom of research for public interest must be weighed against the right to informational self determination. If the scientific analysis will create a positive outcome to benefit public interest it could outweigh the need for extraordinary steps to get consent. It is important to note that doctors and scientific researchers in this case do need to consult with an ethics committee before initiating a research project with sensitive biomaterials related to an individual. [13]

Biobanks research are susceptible to the same standards as research on human beings. Research in biobanks should respect the right to informational self determination. While there is a debate between ethics committees and data protection officers on how broad the information on what research field exactly their biospecimen will go to, the right to self determination still remains. Whether there is a broad scope such as medical research or a specific scope like cancer research the broadness doesn't matter because self determination doesn't specify that the donor be informed to make a decision. It is necessary for the donor

[11] Biobanks for Research, Opinion No. 24/2015, Swiss National Advisory Commission on Biomedical Ethics, online: https://www.nek-cne.admin.ch/inhalte/E_Broschure_NEK_Biobank.pdf
[12] Peter LangKafel et al, Big Data in Medical Science and Healthcare Management, Ch.7 p.91-95, 2014, De Gruyter
[13] Ibidem

to understand that consent can sometimes become uncertain. The donor needs to understand that biobanking is a new field and the future research methods can be uncertain, which may allow for changes in what the specimen are used. Exercising self determination will give answers but it may also be a leap into the uncertainty of a changing field. However, even if multiple parties handle the sensitive data in biobanks, biobank secrecy protects the rights of personality and the right of informational self-determination of the donors against private abuse and against government encroachments. [14]

III. The Consent Dilemma

3.1 Informed Consent

Informed consent is routine in healthcare especially when research is being done on humans. Institutions often recommend obtaining informed consent before performing any sort of research related to humans. Over the years as bioethics has been on the rise, autonomy has become essential in modern medicine. [15] Due to this informed consent becomes a means of assuring patient autonomy in research. [16]

Informed consent is the process between a patient and a doctor where the doctor will give their patient information about certain treatments or possible research taking place and the patient must decide whether or not they wish to go take the treatment or test. The procedure of understanding the risks and benefits of the treatment or test is in fact informed consent. Informed consent is also based on the moral and legal premise of patient autonomy: the patient has the right to make decisions about their own health and medical conditions. Informed consent must be voluntary.

There are three basic components to informed consent. They are disclosure, comprehension and voluntary agreement. Disclosure must be given to the relevant information to the

[14] Human Biobanks for Research, German Ethics Council, 2010 Deutscher Ethikrat, Berlin, ISBN 978-3-941957-12-1

[15] Wolpe, P.R, The triumph of autonomy in American medical ethics. In R. DeVries and H. Subedi (Eds.), *Bioethics and society: Sociological investigations of the enterprise of bioethics*, pp. 38–59. New York: Prentice Hall, 1998

[16] Faden, R.R. and Beauchamp, T.L., *A history and theory of informed consen*t. New York & Oxford: Oxford University Press, 1986

subject on what the research is about. The patient must have comprehension of the information- meaning that they understand the information given to them. Lastly, the patient must give their voluntary agreement free from coercion and undue influence to participate in the research offered. [17]

A study by the Austrian Ethics committee has attempted to demonstrate the reasons why patients may donate their tissues or matter to research. The main reasons were contributing to a functioning system, enhancing medical science and research, and understanding how the system works.

A common logic from a patient in the study was 'because we all benefit from it."[18] This, however, only works in institutions where there is a publicly funded health care system, as their donation as a non-monetary exchange to benefit society as a whole. This would not seem like plausible logic in countries such as the US where expenses are paid out of pocket. In privately funded treatment usually there is no thought of benefitting others since it costs too much. Individuals are usually more motivated to find treatment for themselves only and do not wish their data to be shared with others since they did not pay for such testing or treatments, so they are not as apt to look out for society.

Another response came to be "whatever is needed for good research." [19]Patients believed that they should donate to benefit the medical sciences. They believed that science and research is a gradual process and needs to be updated constantly, and if their donation can help then it is only better in the long run. This logic demonstrates that patients are in it for finding further cures for diseases.

The last thinking is "because consent is needed for everything." They have used the consent procedure because that is simply how the system works. Informed consent is used to protect

[17]Required Components of Informed Consent, Institutional Review Board for Human Participants, Cornell University, https://www.irb.cornell.edu/forms/consent.htm, accessed 22.08.2018

[18] Ulrike Felt, Milena D. Bister, Michael Strassning, and Ursula Wagner, Refusing the information paradigm: informed consent, medical research and patient participation, *An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine,* Vol 13(1): p. 96, 2009

[19] Ibid, p. 97

the relationship between the patient and the medical provider or research operator. This ideal was also demonstrated in the Convention on human rights and biomedicine where it is stated that 'any part of a human body' may only be used 'if this is done in conformity with appropriate information and consent procedures.'[20] Additionally, this was revised in the Declaration of Helsinki where it is explicitly stated that any research on human substances needs to be regulated through informed consent. [21]

3.2 Open Consent and the Data Protection Regulation

Open consent is often the go-to solution in biobanks. It is also known as 'broad consent', 'general consent', and occasionally 'blanket consent.' When using the open consent procedure, a biobank requests consent from the subject for all future research uses of their genetic material and data.[22] It has three identifiers that make it unique from all the other forms of consent. In open consent (1) the research subject is actively giving consent only once to the biobank, (2) the subject is not asked to give consent to a specific research project or to an area of research and the subject gives consent for all future research, the research projects are not clearly defined, (3) researchers who want to conduct research on samples will apply to biobanks to use stored tissues and the biobank decides if they release the material or not the subject themselves have no say in this. [23]

Biobanks are constantly processing personal data, which means that they have a duty to comply with data protection law, which is currently under reform. The changes are relevant for biobanks as the new data protection regulation puts strict criteria on consent conditions. More specifically in open consent the subject only needs to confirm the consent to the biobank once. The consent given is then applicable for the extracted sample, the storage of

[20] Convention on human rights and biomedicine , Council of Europe, 1997: VII, Art. 22
[21] WMA Declaration of Helsinki– Ethical Principles For Medical Research Involving Human Subjects, Articles 25-32
[22] Dara Hallinen & Michael Friedwald, Consent, biobanking and data protection law: can open consent be 'informed' under the forthcoming data protection regulation?, Life Sciences, Society and Policy (2015) 11:1
[23] Ibid, p. 5

the sample and data, and any further research on the collected material. The GDPR explicitly states that any consent should be specific and informed. [24]

3.3 Broad Consent v. Dynamic Consent

The usual norm was to obtain broad consent from individuals participating in biobanks. [25] Biobanks have a hard time to gain fully informed consent as future research in testing of tissues and sensitive matter is often unknown or variable. [26] Currently however there is an alternative form of consent available called dynamic consent. Dynamic consent focuses on the participant and involves ongoing communication between the biobank, donor, and researchers. [27]

Broad consents are not open thus giving broad consent means giving consent to future research of certain types.[28] For this framework to work, each specific research project and independent ethics committee should evaluate projects and the biobank should update their donors with their options on how to withdraw their material. It is important to note that if anything in the framework changes the participants of the study must re-consent. [29] In the broad consent model, people are asked to re-consent only when there is an ethically relevant difference between two projects.[30] If such a situation occurs, participants are then asked to re-consent, because a research ethics committee or the biobank believes there is something more to ask them about.

[24] Article 4(11) GDPR
[25] Steinsbekk KS, Myskja BK, Solberg B, Broad consent versus dynamic consent in biobank research: is passive participation an ethical problem? Eur J Human Genet 21:897–902, 2013
[26] See further: Kaye J, Whitley EA, Kanellopoulou N, et al., Dynamic consent: a solution to a perennial problem? BMJ, 2011
[27] Dorit T. Stein and Sharon F. Terry, Reforming Biobank Consent Policy: A Necessary Move Away From Broad Consent Toward Dynamic Consent, Genetic Testing and Molecular Biomarkers, 17:12, 2013
[28] Hansson MG, Dillner J, Bartram CR, Carlson JA, Helgesson G: Should donors be allowed to give broad consent to future biobank research? Lancet Oncol 2006; 7: 266–269.
[29] Steinsbekk KS, Solberg B: Biobanks– when is re-consent necessary? Public Health Ethics 2011; 4: 236–250.
[30] Ibid

Dynamic consent is a 'personalized, digital communication interface,' which allows biobanks/researchers to establish continuous communication with research subjects.[31] In this model, subjects are presented with specific project options and can constantly update their consent preferences in accordance with what studies they want to participate in and what they want do with their samples.

With a dynamic consent model, participants will be asked for consent constantly because each project is considered a new project. [32]Therefore, the participants will be asked to re-consent both for essential and non-essential reasons. With broad consent participants are seldomly asked to re-consent, but when they are asked it is for an important reason or change in the research or testing.

I think that the most appropriate form of consent in biobanking is dynamic consent. Dynamic consent allows for constant communication with the tissue donors and for them to change their preferences allowing them to be in control of where their materials go and to what study. The fact that the dynamic consent model informs research participants about the research they are involved in is essential in all types of research consent processes. This method better distributes detailed information compared with broad consent. Additionally, dynamic consent increases trust and willingness to participate in research. The aim of dynamic consent is to be more inclusive compared with regimens utilizing broad consent.

This method of consent is also more applicable with the GDPR as it provides a specific and informed explanation of where the sample will be used and for what purposes. On the other hand, dynamic consent seems to go against Article 9(2) with regards to sensitive data, but this is a good thing as it can be an infringement of fundamental rights.

[31] Kaye, Jane, Edgar A Whitley, David Lund, Michael Morrison, Harriet Teare and Karen Melham. 2014. Dynamic consent: a patient interface for twenty-first century research networks. European Journal of Human Genetics 1–6., p.1
[32] Kristin Solum Steinsbekk, Bjørn Ka˚re Myskja, Berge Solberg, Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?, European Journal of Human Genetics (2013) 21, p. 898, 2013

3.4 Anonymization and Consent in Biobank Research

The term ‘anonymized’ means that biological material is stored in conjunction with related information, such as medical treatment, donor’s age and so on, but all information that would allow identification of the research participant or patient is kept secret, either irreversibly (unlinked anonymized) or reversibly (linked anonymized). If the sample is linked anonymized, identification is possible by a code, to which researchers or other users of the material do not have access. In European documents, the term anonymized could mean either unlinked or linked anonymized. In the EU, ‘coded’ always indicates that researchers or other users have access to the code.

According to many regulations and guidelines, there is no need to destroy a sample when a participant withdraws from a study, since anonymization can solve the problem. The European Society of Human Genetics writes that the use of ‘unlinked anonymized samples’ secures ‘absolute confidentiality’ and these samples can be used for new purposes without obtaining consent.[33] The International Bioethics Committee (UNESCO) clarifies that consent may be withdrawn by the donor ‘unless such data are irretrievably unlinked to an identifiable person’ and that the data and biological samples should be treated as the donor wishes unless they are permanently unlinked.[34]The German Nationaler Ethikrat states that when samples are anonymized, then ‘donor interests calling for protection are not at issue’ and withdrawal of consent can be combated with anonymization.[35]

The argument for anonymization is linked to the fact that information derived from a participant’s tissue cannot be used at their disadvantage if no one can find out their identity. The data subject does have the right to end participation in a study, but since it can be of importance to keep the sample for research, de-identification is the more preferred solution. Anonymization means that the participant is no longer participating; only the anonymous tissues are being observed, with no researchers gaining access to the identity of the donor.

[33] Godard B, Schmidtke J, Cassiman JJ, Ayme S: Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective. *Eur J Hum Genet* 2003; **11** (Suppl 2): S88–S122.
[34] UNESCO: International declaration on human genetic data. *Eur J Health Law* 2004; **11**: 93–107
[35] Nationaler Ethikrat: *Biobanks for research, opinion*. Berlin: Nationaler Ethikrat, 2004.

However, anonymization has some flaws in protecting participants' interests:

1. It may not decisively cut the link to a specific individual,
2. It prevents the use of samples for purposes such as diagnostics,
3. It may not prevent harms to groups, and
4. It does not rule out wrongdoing.[36]

The ties from the individual cannot easily be cut. Genetic information can be stored in medical journals, if an anonymous sample is run against a search of these journals, it can reveal whose sample it is. The publication of databases on the Internet, free for researchers to use, presents dangers to anonymity. If access of an identified sample is gained, more samples from the same person can be found by searching databases consisting of anonymous samples and comparing them.

Anonymization prevents samples to be used for medical services. This is due to the fact that if a sample is de-identified it can no longer be used for diagnostics. Many individuals want to contribute to the medical world by offering their samples for the use of medical services, do not understand that protecting this sensitive information through anonymization does not leave them that option.

On top of anonymization not protecting the interests of participants, anonymization of biobank samples may have a negative impact on research. For many studies, it is essential that researchers or those in charge of the biobank, have access to the identity of the samples so they can be linked to medical journals and register data. For quality reasons, researchers may also need to return to the original repository. A model in which continued use of identified samples is impossible if withdrawal is requested seems unsatisfactory, but anonymization also does not have all the answers quite yet.

Anonymization should not be the default setting for researchers and biobank holders when requests of withdrawal occur. On the other hand, a request for withdrawal should not stop research on identifiable samples. Instead of the present emphasis on individuals' right to

[36] Stefan Eriksson & Gert Helgesson, Potential harms, anonymization, and the right to withdraw consent to biobank research, *European Journal of Human Genetics* volume 13, pages1071–1076 (2005)

withdraw consent to research on their biological samples for any reason, the clause on withdrawal in the Nuremberg Code be included in guidelines on biobank research.[37] This would allow anonymization as a solution to the withdrawal of samples and promote further research on the tissue in question. Although there would also have to be reforms on researchers requests of the samples and a way to ensure that the information of the donor doesn't get released through medical journals.

3.5 Privacy Self-Management

The new General Data Protection Regulation states that personal data may only be processed based on one of the following six grounds: it is required by a legal obligation, it is carried out to protect a vital interest of the individual, it is carried out for the public interest, it falls within a legitimate interest of the data controller, it is necessary for the performance of a contract, or it is based on the consent of the individual.[38] Consent for our purposes is an essential addition to the GDPR, particularly informed consent, which allows the individual to agree to data processing options and who gets access to their data. Privacy self-management allows people the right to take notice of how their personal data is being collected and used and need to decide whether or not they consent to such use of their data.

Daniel J. Solove coined the term 'privacy self-management' as a bundle of rights providing people with control over their personal data, through which individuals can decide for themselves the costs and benefits of collecting, using, or disclosing their information. [39] Privacy self-management takes a neutral stance on whether certain forms of collecting data or good or bad, and actually focuses on individuals consent to various privacy practices.

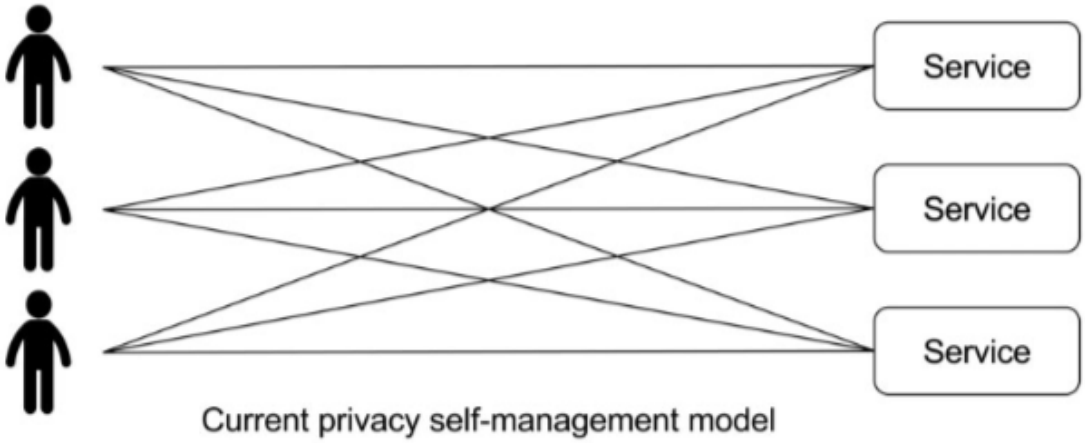
Privacy self-management originates from the Fair Information Practices, also commonly referred to as the Fair Information Practice Principles (FIPPs). [40] The FIPP was discussed in

[37] Ibid
[38] Tuukka Lehtiniemi and Yki Kortesniemi, Can the obstacles to privacy self-management be overcome? Exploring the consent intermediary approach, Big Data & Society July-December 2017: 1-11
[39] Daniel J. Solove, Introduction: Privacy Self-Management and the Consent Dilemma, Harvard Law Review, Vol. 126:1880, 2013
[40] Robert Gellman, *Fair Information Practices: A Basic History*, Bob Gellman 9–10, 2012, Online: https://bobgellman.com/rg-docs/rg-FIPshistory.pdf

a report to discuss concerns about data being increasingly digitized. FIPP principles included (1) record systems of personal data must be transparent, (2) individuals should be able to find out about such record systems, (3) the right to prevent personal data from being used for new purposes without consent, (4) the right to correct or amend one's records, and (5) responsibilities on the holders of data to prevent its misuse.[41] These principles helped shape the OECD Privacy Guidelines of 1980 and the APEC Privacy Framework of 2004.[42]

While privacy self-management can provide benefits there are a few problems that arise.

1. Individuals usually do not read privacy policies
2. If the policies are read, they are not always understood
3. If the privacy policies are read and understood, then individuals do not have enough information to make an educated and informed decision
4. If the terms are understood decision-making can always be skewed making it hard to make an informed decision.



Current privacy self-management model

Although privacy self-management seems like it can be good for the individual, the individual still cannot appropriately self-manage their data. The problem of scale comes into play. The problem of scale is related to the number of companies collecting and using data, making it impossible for an individual to be able to manage privacy with everyone individually. Another example is the problem of aggregation. The problem of aggregation

[41] U.S. Department of Health, Education & Welfare, Report of the Secretary's Advisory Committee on Automated Personal Data Systems: Record Computers and the Rights of Citizens, 41-42, 1973, Online: https://www.justice.gov/opcl/docs/rec-com-rights.pdf
[42] Daniel J. Solove, Introduction: Privacy Self-Management and the Consent Dilemma, Harvard Law Review, Vol. 126:1880, 2013

is the fact that privacy harms often consist of an aggregation of different pieces of data. Thus, an individual has no way to assess whether any information disclosed about them, when combined with other data, can reveal something that can cause them harm later down the road.

Privacy law often relies too much on privacy self-management. Privacy self-management cannot achieve privacy alone. Many privacy issues are inherently linked with the consent dilemma. A coherent approach to consent must be developed in legal framework, taking into account how individuals actually make decisions about their personal data. It is also important to develop more substantial privacy rules and timing necessary for consent. While, an individual can take part in privacy self-management it is important to remember that individuals can often only participate in this selectively and if they fully understand what they are consenting to.

3.5.1 Information Privacy and control of personal data

Informational self determination is an updated form of the right of privacy, protecting citizens from the unlimited gathering, storage and use of private information. It is considered the right of private individuals to know who is collecting and using information about them at any given time and under any circumstances. The right of informational self determination prevents enterprises or government agencies from doing whatever they want with the data of private citizens. This legislation guarantees the fundamental right of individuals to determine whether and how their data should be used or released.

The German Constitutional Court has developed the right to informational self-determination in 1983, in its famous Census decision (Case No. 1 BvR 209/83, 15 Dec. 1983, 65 BVERFGE 1.) The court declared the Census Act of the Federal Parliament unconstitutional based on the provisions of Article 1 (human dignity) and Article 2 (right to free development of personality) and ruled that “basic right warrants […] the capacity of the individual to determine in principle the disclosure and use of his/her personal data,” and further “the authority of the individual to decide himself, on the basis of the idea of self-

determination, when and within what limits information about his private life should be communicated to others." [43]

One of the biggest dilemmas in data protection of personal data has been finding a balance between informational self-determination and an individual's control over their data with the competing interest of the one's collecting, using and processing their data.

A patients' genetic data is considered sensitive data. This encompasses all personal data, which is particularly sensitive in relation to fundamental rights and freedoms, meriting specific protection as the context of their processing could create significant risks. It is forbidden to share such personal data especially a patient's health and genetic data, the only exception to this is if it falls under Article 9, paragraph 2 of the General Data Protection Regulation.

Under Article 9, paragraph 2 such information can be given up only for a few reasons, encompassed below.

1. If the patient gives explicit and unambiguous consent to the use of their data
2. If the patient makes the data manifest himself or herself
3. If it is in the patient's vital interest
4. For healthcare purposes
5. For public interest in the area of public health
6. To carry out the right of the person that controls patients' data in the field of employment, social security and social protection law
7. Substantial public interest
8. Processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes[44]

[43] Rouvroy Antoinette, Poullet Yves. The right to information self- determination and the value of self-development: reassessing the importance of privacy for democracy, 2009, p.45
[44] The new EU Regulation on the protection of personal data what does it mean for patients, A guide for patients and patients' organizations, European Patients Forum, Online: http://www.eu-patient.eu/globalassets/policy/data-protection/data-protection-guide-for-patients-organisations.pdf, accessed September 1st, 2018

Regulation 2016/679 provides a lot of insight for the protection of personal data. This new regulation aims to empower people of their rights and the right to be informed gives them more control over their personal data. These protections are highly relevant for patients in healthcare and provide answers for research purposes as well. The details can be reviewed in the chart below.

Right Provided	**Article Number**	**What's in it for the patient?**	**What to be careful of**
To access one's own personal data	Recital 63 Article 15	• The right to access your personal data is part of your fundamental right to data protection • The right to access your medical record is explicitly mentioned in the new Regulation • If you request a copy of the personal data being processed by a data controller about you, they are obliged to provide it to you	• The controller can charge a fee for the administrative cost of providing the data when you request it more than once. Article 12 also explains that a fee can be charged when the request for data is "unfounded" or repetitive. • If you provided your data in the context of a scientific research, there may be exemptions to this right
Right to data portability/to transfer your data from one data controller to another	Article 20	• When you have consented to provide your health data, and that it is in a machine readable format (e.g. in electronic form), you can request to receive a copy in order to transfer it to another entity or person, and you can also demand that it is transferred directly for you	• There is no firm obligation for controllers to ensure the data is easily transferable

Right Provided	Article Number	What's in it for the patient?	What to be careful of
Right to object to the processing of your data	Article 21	Under the new regulation you can object to the processing of your data by a controller under these circumstances: • If the processing happens for a task performed in the public interest (Article 6 paragraph 1(e)) • If the processing happens for the legitimate purpose of the controller (Article 6 paragraph 1(f)) • If it happens in the context of direct marketing	In research, you can object to the processing, unless it is necessary for a task carried out for reasons of public interest (Article 21 paragraph 6)
Right to rectification or erasure of data	Article 16	You can ask for the rectification of inaccurate personal data (e.g. in your medical record) and incomplete data completed.	
Right to be forgotten	Article 17	You can have your data erased. This is especially the case if: • you have withdrawn consent and the data controller has no other grounds for processing your data • if there is no longer a purpose for processing it, in accordance with the principle of limited storage and data minimization. • if the processing is unlawful in the first place	There are derogations to your right to have data erased in research and in healthcare.

Right Provided	Article Number	What's in it for the patient?	What to be careful of
Rights when there is a breach	Article 34	If there is a security breach and your personal data is unduly disclosed, accessed, or destroyed, the data controller should keep you informed about the breach if it is a threat to your rights or freedoms, unless they have taken other measures to protect the data (like key coding the data). They should also inform their national supervisory authority of the breach.	It is important to ensure that supervisory authorities are accurately informed of the threat to rights and freedoms represented by undue disclosure of health or genetic information.
Right to be informed/transparency	Article 13, 14	The data controllers have an obligation to provide some information to you. They have to provide it in a concise, transparent, intelligible and easily accessible form, using clear and plain language.	There is an exemption, in the case of research, if it proves to be a "disproportionate burden" to provide this information to data subjects. When data subject's requests for information are "unfounded" or repetitive, controllers can charge you to provide this information (Article 12)

Table 1 EU Law regarding patient rights to data privacy[45]

While discussing biobanking and data protection of adults it is vital to note that biobanking samples of children is increasing at an even higher rate. This has become the case because the percentage of disorders with genetic backgrounds is greater than those in adults. [46] The Netherlands has several large-scale pediatric biobanks such as the Amsterdam-Born Children and Their Development Study (ABCD)[47] and the KOALA cohort study.[48] Pediatric biobanking faces traditional challenges of biobank privacy protection along with

[45] The new EU Regulation on the protection of personal data what does it mean for patients, A guide for patients and patients' organizations, European Patients Forum, Online: http://www.eu-patient.eu/globalassets/policy/data-protection/data-protection-guide-for-patients-organisations.pdf, accessed September 1st, 2018

[46] Verma IC, Puri RD (2015) Global burden of genetic disease and the role of genetic screening. Semin Fetal Neonatal Med 20(5):354–363

[47] ABCD Study, http://www.abcd-studie.nl/?page_id=238. Accessed 30 March 2020

[48] KOALA Study, https://www.koala-study.nl/node/12645. Accessed 30 March 2020

additional challenges. Specific additional challenges are related to the young age of donors which hinders responsible decision-making capacity legally. The rights of these children need to be protected at all points. While initially the rights are initially exercised by their legal representatives the children gain access to exercise their rights, thus it is essential that the information is handled properly and with proper transparency. One question I came upon and will focus on with child pediatric cases is what rights do a child's legal representatives have to control whether the child's samples will be stored in a biobank, and what rights does that child later have upon reaching the legal age of decision-making capacity? [49]

The Convention of the Convention on Human Rights and Biomedicine (CHRB) from the Council of Europe (1997)[50] is a good place to start to examine these issues. According to article 5 and 6 of this convention together with the (non-binding) International Declaration on Human Genetic Data[51], free and informed consent to storage of a child's residual samples should be authorized by the child's parents or representatives. Additionally, the Biomedicine Convention confirms people's 'right to know' any data collected about their health as well as 'their right not to know.' 'The right not to know' simply means that they do not wish to be informed of information or they do not wish to access it. This right to not know is interesting to note in cases of children with mental disabilities because the children may never have the power to comprehend the information but their parents or guardians can use the genetic research to help others with similar cases to gain more information on particular genetic mutations. However, it is important to note that these rights are not

[49] Elcke J. Kranendonk, Raoul C. Hennekam, M. Corrette Ploem, Paediatric biobanking: Dutch experts reflecting on appropriate legal standards for practice, Eur J Pediatr (2017) 176:75–82

[50] Council of Europe (1997) 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. Oviedo: Council of Europe. Online: https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168007cf98

[51] United Nations Educational, Scientific and Cultural Organization (UNESCO) (2003) International declaration on human genetic data, Paris.Online: http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

absolute and can be overruled in a case of vital interests or donors or their relatives according to paragraph 70 CHRB Explanatory report. [52]

The second international guideline that is relevant to children, while has little mention on their explicit right, is the Guidelines on Human Biobanks and Genetic Research Databases (HBGRD). Paragraph 45 of the CHRB Explanatory Report does note that the opinions of minors should carry increasing weight in decisions in keeping with their age and maturity. This issue of affirming children's right to express their own opinions, is similarly tackled in article 12.1 of the United Nations Convention on the Rights of the Child (UNCRC): 'States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.' These two conventions help to ensure that while the child does have a guardian that tackles their biobanking information while they are not capable, the child does have a right to have a say and weigh in on their personal choices when they are mature enough. However, it is interesting to note that in the conventions it is never concretely specified what is maturity and how to explicitly evaluate it in different cases.

Notably, the Dutch legislative framework permits adolescents aged 16 and older in principle to decide independently about their treatment and, after acceptance of an amendment bill, about participating in biomedical research.[53] While this is progressive to allow children to have control over their data at a young age it seems to make the matter more complex. It is complicated to inform a child at an adolescent age about their rights since the matter may be too complicated for their young mind to comprehend fully. On the other hand, it seems like a great step in transparency and easy accessibility to information they are entitled to and should be followed up on if the child is involved and comprehends the totality of their actions. The right to termination in special requests of the child donor

[52] Council of Europe (1996) Explanatory report to the Convention on Human Rights and Biomedicine. Strasbourg: Council of Europe. Online: https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016800ccde5.

[53] Elcke J. Kranendonk, Raoul C. Hennekam, M. Corrette Ploem, Paediatric biobanking: Dutch experts reflecting on appropriate legal standards for practice, Eur J Pediatr (2017) 176:75–82

should be valued in accordance with the unique Dutch law provided. However, children under 16 do not yet qualify for independent consent does not mean that they do not need to be informed about their participation and should not be involved in the decision-making process.

All children have the right to be informed and should be able to take part in the process since later in life they will have the power to control their biospecimen in the future. It is inherent to keep them up to date so they can make a knowledgeable decision when the time comes for them to take charge if they are willing.

IV Biobank Regulation and Data Protection

Biobanks form a key infrastructure layer supporting genetic research. However, as biobanks have become more popular and the importance of samples and data in research has grown collecting samples with no particular purpose has been essential in the industry to analyze expanding data sets. [54] The current strict conditions on traditional consent methods in medical research are contradictory for biobanks, there is a requirement to specify the specific research in advance and to gain consent from the participants, which is directly going against the method of biobanks to extract maximum research necessary to yield results in collecting samples.

There are arguments in place today that biobanks are a unique research concept and should be given some leeway. Such ideas are backed up by pro-autonomy and self determination concepts. There are two-sides to this coin, on the one side it can be argued that biobanking has a lot of potential on health research and that these strict requirements can hinder the huge research yields that biobanking can provide in the health sector.[55] On the other side, it

[54] Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research, 2013

[55] Hansson, Mats, Joakim Dillner, Bartram Claus, Carlson Joyce, and Gert Helgesson, Should donors be allowed to give broad consent to future biobank research?, Lancet Oncology 7: 267, 2006, p. 267

can be argued that such physical risk that comes with invasive research is different to the informational risk that is ever present in biobank research. [56]

Simple storage of a sample in a biobank, however, doesn't involve any direct physical harm. According to the German Nationaler Ethikrat, bodily risks are prohibited from the start because the samples being used for research are already separated from the body.[57] This means that there is a distinct difference between biobank research and research conducted directly on the human body. In fact, the Declaration of Helsinki states that medical research involving human subjects 'includes research on identifiable human material or identifiable data.'[58]

Although there is no direct physical harm, this does not mean that there is no other types harm in biobank research. There is indirect physical harm. Samples collected in a clinical setting are important for future care of patients, with many parties interested in the results of the testing on sampling and potential solutions they may yield as a whole in the medical world. If researchers gain unrestricted access, samples can be over sampled/ overused, and this will lead to sparse samples for future care. This could in turn not just harm the research sphere but can lead to side effects for patient's physical health over time since they may need more samples from the patient and will not provide results.

Another common form of harm see in biobank research is nonphysical harm. Nonphysical harm means that sensitive information has ended up in the wrong hands and is being exploited to disadvantage an individual. The information is extracted from samples. If the biobanks are implementing a high safety standard, then the nonphysical risk is relatively small. A frequent example of this is demonstrated with the insurance companies using genetic information to discriminate against people with certain genetic dispositions. [59] This

[56] See: Mascalzoni, Deborah, Andrew Hicks, Peter Pramstaller and Matthias Wjst, Informed Consent in the Genomics Era, PLOS Medicine 5: 9, 2008
[57] Nationaler Ethikrat: Biobanks for research, opinion. Berlin: Nationaler Ethikrat, 2004.
[58] Stefan Eriksson and Gert Helgesson, Potential harms, anonymization, and the right to withdraw consent to biobank research, European Journal of Human Genetics (2005) 13, p.1072
[59] Stefan Eriksson and Gert Helgesson, Potential harms, anonymization, and the right to withdraw consent to biobank research, European Journal of Human Genetics (2005) 13, p.1072

kind of discrimination can lead to economic and social harm to the individual. [60] That is why many individuals get concerned with keeping their privacy safe since facts that an individual may want to keep private are communicated to others without their consent, psychological or social harm may arise, particularly stigmatization and discrimination at work, as anxiety and disturbed relationships. [61]All these three potential harms are why there is a debate and need for protection of privacy to be in force for patients, as well a way to withdraw information if necessary.

The GDPR protects individuals with regard to the processing of personal data and on the free movement of such data. It has been transposed into national law. The objective of this Regulation is to secure the free flow of personal data within the internal market making sure to ensure a high level of protection for all citizens and their consent procedures through the process. Health data has special protection within Article 9(1) of the GDPR where the processing of sensitive data in general is prohibited. Still, the protection is not absolute and there are circumstances where the public interest overrides the privacy interests of the individual. This is due to the fact that health data is highly sensitive and therefore requires a high level of protection. Biobanks as an infrastructure for research were still unknown at the time the GDPR was drawn up, so it is not easy to find the right category for them. [62] Due to the lack of popularity of biobanking at the time biobanks are not explicitly mentioned in the regulation. Biobanks are not research themselves, but they belong to the wider research domain. Thus, biobanks for health research can also be seen as public health tools as they share many legal features with monitoring and surveillance institutions. [63]

The principle of purpose, in combination with the principles of non-excessiveness and fairness, with regard to data collections like biobanks is described in Article 5 and 9(2) of

[60] Radetzki M, Radetzki M, Juth N: Genes and insurance. Cambridge: Cambridge University Press, 2003.
[61] Eriksson S: Should results from genetic research be returned to research subjects and their biological relatives? Trames J Humanities Soc Sci 2004; 8: 46–62.
[62] Tobias Schulte in den Baumen , Danielle Paci, Doloris Ibarreta, Data Protection and Sample Management in Biobanking – A legal dichotomy, Genomics, Society and Policy, Vol.6, No.1 (2010) ISSN: 1746-5354
[63] M. Verschuuren et al. The European data protection legislation and its consequences for public health monitoring: a plea for action. Eur J of Public Health 2008; 18(6): 550-551

the GDPR. Article 9(2) highlights the data protection problems that biobanks are currently facing. Large-scale population-based biobanks require substantial investments and are part of a long-term infrastructure for medical research. Accordingly, from the research perspective, the purpose is exactly to serve as a tool for long-term genome-based research.[64] The Data Protection Regulation states that the purpose of the processing must be legitimate and explicit at the time of the data collection.

4.1 Consent in Biobanking

Biobanks are constantly processing personal data, which means that they have a duty to comply with data protection law, which is currently under reform. The changes are relevant for biobanks as the new data protection regulation puts strict criteria on consent conditions.

Under the GDPR specific mechanisms must be set in order for consent to be valid:

- Data subjects are provided with a clear explanation of the processing to which they are consenting;
- The consent mechanism is genuinely of a voluntary and "opt-in" nature;
- Data subjects are permitted to withdraw their consent easily;
- The organization does not rely on silence or inactivity to collect consent.

Additionally, the Regulation specifies the criteria on consent should be obtained:

- If the data subject's consent is given in the context of a written declaration, which also concerns other matters, the request for consent shall be presented in a manner that is clearly distinguishable from the other matters.
- Consent must be requested in an intelligible and easily accessible form, using clear and plain language.
- Consent must be freely given.
- Consent must be informed, as specified in the GDPR.
- Consent must be provided by a clear and affirmative action.
- Consent can be provided in writing, by electronic means, as well as orally.

[64] Opinion of the German Nationaler Ethikrat. 2004. Biobanks for Research: 28-31. http://www.ethikrat.org/_english/publications/Opinion_Biobanks-for-research.pdf

Article 4(11) of the GDPR defines consent as: “any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.” In addition to the amended article 4(11) guidance on how to comply with the main elements of consent are laid out in Article 6, 7 and in recitals 32, 33, 42, and 43. Lastly, provisions and recitals are included on the withdrawal of consent confirms that consent should be a reversible decision and data subject has control over this.

As biobanks process ‘personal data’, European data protection law applies in their day-to-day operations. Despite the clear evidence that data protection law applies, there remains uncertainty about the exact application of the regulation. There are questions if open consent is legitimate is one such uncertainty. On top of this there is a wide range of opinions on what types of consent is applicable in the use of sensitive data. In addition to this, the GDPR requires that any consent be ‘specific’ and ‘informed’. This could pose a problem for biobanks operating with open consent as they cannot meet these requirements.

Processing of personal data in biobank-based research involves sensitive data, such as health and genetic information, socio-demographic data, lifestyle and behavioral data provide requirements on regulation of such data. Additionally, principles for fair processing are addressed in the regulation stipulating that data protection supervisory authorities should provide oversight and supervisory roles. [65]

4.1.1 The right to withdraw to Biobank research

Thanks to the Declaration of Helsinki 1964 the demand for unrestricted individual rights to withdraw consent to participate in research is on the rise. According to the Helsinki Declaration, all research subjects have the right to withdraw consent to participate at any time without punishment, regardless whether the research was conducted on their bodies or

[65] Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research. 2013. Biobanks for Europe: A Challenge for Governance. Directorate-General for Research and Innovation. http://ec.europa.eu/research/swafs/pdf/pub_archive/biobanks-for-europe_en.pdf. Accessed 28.05.2018

on their stored biological samples. [66] Although there was already the concept of individual rights in to stop participation in studies before in the Nuremberg Code of 1947, the Helsinki Declaration provided a clearer, easier way on how to do this.

The Nuremberg Code saw research, as a common good and idealized experimental subjects, as a greater good for humanitarian projects leading to different view on withdrawal rights[67], whereas the Helsinki Declaration provided the individual the right to withdraw regardless of the reasoning allowing for more freedom. The right to withdraw consent does not imply a right to withdraw results that have already accumulated, rather it implies that new data cannot be obtained, and that existing data must be maintained in an impersonalized form. [68]

The Council for International Organizations of Medical Sciences (CIOMS) states in its International ethical guidelines for biomedical research involving human subjects that informed consent ‘‘protects the individual’s freedom of choice and respects the individual’s autonomy’’ and that research participants should be informed when they ‘‘will be free to withdraw from research at any time without penalty or loss of benefits to which he or she would otherwise be entitled.”[69] It should be noted that researchers should never conduct research without consent form the participants, however CIOMS allows exceptions. CIOMS only exception is when an ethical review committee gives its approval, this can be done if the research is considered important enough and involves no more than minimal risk, the rights and interests of the subjects are not violated, and privacy and confidentiality are assured. [70] Individual consent should only be mandatory is the researcher cannot prove that the consent is a big obstacle that will make the research unviable. [71]

[66] World Medical Association. Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, 2004, online: http://www.wma.net/e/policy/b3.htm.
[67] See further: The Nuremberg Code, 1947, BMJ 1996
[68] Hansson, Mats, Joakim Dillner, Bartram Claus, Carlson Joyce, and Gert Helgesson, Should donors be allowed to give broad consent to future biobank research?, Lancet Oncology 7: 267, 2006
[69] CIOMS: 2002, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva, General Principles
[70] Gert Helgesson and Linus Johnsson, The right to withdraw consent to research on biobank samples, Medicine, Health Care and Philosophy (2005) 8:315–321
[71] CIOMS: 2002, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva, Guideline 4

The right to withdraw consent is also protected in the Convention on human rights and biomedicine. Article 5 of the Convention on human rights and biomedicine, issued by the Council of Europe, states that all research subjects ‘‘may freely withdraw consent at any time.[72]’’ This is backed up in the convention with Article 2, which states that the ‘‘interests and welfare of the human being shall prevail over the sole interest of society or science.[73]’’ Although research specifically on biological materials is not explicitly stated the Explanatory Report that the convention encompasses ‘‘all medical and biological applications concerning human beings’’[74], including research.

Article 7(3) of the GDPR prescribes that the controller must ensure that the data subject can withdraw consent as easily as they can give consent and at any given moment. The GDPR does not say that giving and withdrawing consent must always be done through the same action. The requirement of an easy withdrawal is described as a necessary aspect of valid consent in the GDPR. If the withdrawal right does not meet the GDPR requirements, then the consent mechanism of the controller does not comply with the GDPR. In addition to this, controllers have an obligation to delete data that was processed on the basis of consent once that consent is withdrawn, assuming that there is no other purpose justifying the continued retention.[75]

According to extensive research most ethical guidelines are for the protection of withdrawal of consent in biobank research. However, there are no explicit explanations as to why this should be an available remedy within these documents. Invoking the right to withdraw consent is important for the public to have trust in researchers and will promote more participants if they know they have an option to opt-out or remain in the biobank research process.

72 Council of Europe: 1997, 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, Oviedo, article 5
73 Ibid, article 2
74 Council of Europe: 1996, Explanatory Report to the 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, paragraph 10
75 Article 29 Working Party[SEP]Guidelines on consent under Regulation 2016/679

4.2 Legal Application of Biobanking

4.2.1 The US

The case AMP v Myriad had a verdict drawn down from the Supreme Court that simply identifying a particular DNA gene sequence is not sufficient enough to grant the person who identified it a comprehensive and exclusive patent regarding said sequence. This case is interesting in observing patents of biological materials and is interesting to apply in the case of academic research patenting and its freedom, which will be discussed further in the chapter.

Myriad Genetics, Inc. is a genomic research firm whose mission is to learn what various sequences of DNA in the human genome actually do. In the course of their research, and in collaboration with other scientists from other groups, Myriad's scientists made an extraordinarily useful discovery of two genes now known as BRCA1 and BRCA2. The influence of these genes can elevate the risk of a woman developing cancer.

As a result, after the discovery was made, the company began offering screening tests to members of the public able to afford them and filed for patents related to the discovery and associated assets. Certain patents were granted, and Myriad claimed exclusivity over various tests and other items related to the genes in question.

Myriad's claiming exclusivity was controversial and problematic for many reasons. If valid, the patents essentially would give Myriad "ownership" of the genes, for practical purposes and applications. This ownership could have been used to impede scientific progress and health care efforts including the prevention of:

1. Academic researchers from pursuing studies in connection with the genes;
2. Labs from offering tests related to the genes; and
3. Medical professionals from offering treatments related to the genes.

A coalition of petitioners from academic researchers, labs and medical professionals filed suit seeking to have Myriad's patents invalidated so that research, tests and treatments related to the BRCA1 and 2 genes could be pursued unrestricted.

Myriad argued that once a gene is isolated, and distinguishable from other genes, it could be patented. By patenting the genes, Myriad gained exclusive control over diagnostic testing and further scientific research for the BRCA genes. Petitioners argued that patenting those genes violated §101 the Patent Act because they were products of nature. They also argued that the patents limit scientific progress. §101 limits patents to "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."

The questions the court had to deal with were:

1. Can genetic research resulting in a major scientific breakthrough be considered patentable subject matter given its contribution to science and the humanities?
2. Patentable research does not distinguish between natural occurring versus synthetically made genetic segments?

The court decided that patentable subject matter does not rely upon "major scientific breakthrough" accomplishments or mannerism of its "contribution to science and humanities", its sole patentable evaluation should be based on statutory constructs of "Novelty, Utility, Non-Obviousness", balanced with statutory patent ineligible subject matter of "Natural Phenomenon, Law of Nature, Abstract Ideas." The court adjudicated that natural occurring genetic segments are patent ineligible based on statutory bar of "Natural Phenomenon, Law of Nature" since the segments already existed without human intervention and were only identified by humans for latter scientific research. On the other hand, synthetically made genetic segments are considered patentable subject matter since they do not occur naturally in nature, thus created specifically by human intervention.

In the end, the Supreme Court held that Isolated DNA was patent ineligible, but synthetic Composite DNA was patent eligible under 35 USC 101.

This case paved the way in the scientific patenting world of the US, but it also shone a light on how collaborative research should be handled. The idea that no naturally human derived materials can be patented especially on a collaborative project shows a parallel as to some issues discussed later on university run biobanks. The court case here could help in future cases not just in the scientific community but also in researcher communities for further

biobank studies, it can also provide a good example on abolishing the concept of 'professor's privilege.'

4.2.2 The UK

Human rights often come into play in biobank regulations and as an example of such recently there have been cases discussing informatization of the body.

Informatization of the body is 'a process where the human body is recast as an entity constituted by information.'[76] Informatization of the body undermines the traditional distinction between the body itself and information about the body. Van der Ploeg argues that the body and data can no longer be separated and that informatized bodies have moral and legal obligation to be protected. [77]

In short, this means that the body is considered an entity made of information. This is referring to the fact that the medical industry is using the body as a source of gathering data, so in essence, separating the body and using the samples extracted as a source of information rather than seeing the physical body. For instance, this can be seen in all our information going in patient records in databases and registries so other medical professionals can access our data.

There was a case in the EU that merged the idea of the Data Protection Convention and human rights. The Data Protection Convention should protect rights and freedoms of the research subjects' matter. Particular focus should be given to article 8 of ECHR and the Data Protection Directive. [78]Strasbourg case law has demonstrated that ECHR article 8

[76] Lee A. Bygrave, The Body as Data - Biobank Regulation via the Back Door of Data Protection Law, 2 Law Innovation & Tech. 1, 2010, p. 6
[77] See further: Irma van der Ploeg, Genetics, Biometrics and the Informatization of the Body', 2007, 43 *Annali dell' Istituto Superioredi Sanith 47*
[78] Lee A. Bygrave, The Body as Data - Biobank Regulation via the Back Door of Data Protection Law, 2 Law Innovation & Tech. 1, 2010, p. 11

requires the processing of personal data to be regulated in accordance with basic data protection principles. [79]

The Grand Chamber of the European Court of Human Rights (ECtHR) held that regulation in England, Wales and Northern Ireland for the retention of the fingerprints, cellular samples and DNA profiles of particular persons breach the European Convention on Human Rights (ECHR). The exact wording of the court was:
"The Court notes at the outset that all three categories of the personal information retained by the authorities in the present case, namely fingerprints, DNA profiles and cellular samples, constitute personal data within the meaning of the Data Protection Convention as they relate to identified or identifiable individuals." [80]

The Marper case ruling could be used to argue that personal data should encompass biological material. The UK Information Commissioner's Office (ICO) in addition with a consultation paper builds on the *Marper* case to argue that 'the processing of personal data in the form of DNA *samples* and profiles and fingerprints *clearly engages'* central provisions laid out in the UK Data Protection Act. [81] The court's decision regarding personal data can be seen as a stretch because there is no express definition of biological matter being 'personal data' in the Data Protection Convention. There is article 2(a) that speaks of 'any information relating to an identified or identifiable individual' but the explicit terms of data and information are otherwise unspoken for. [82]

On the one hand, the Marper case brought to light the issues of human rights and data protection, but on the other, there seem to be some pieces missing to make this always a binding precedent. This case is a good start to recognizing that human rights and data protection should be considered together in data protection cases. This case also pushes the Data Protection Convention to be more directly applicable to biobanking. While it is

[79] Lee A. Bygrave, Data Protection Pursuant to the Right to Privacy in Human Rights Treaties, 1998**,** 6*InternationalJournalofLaw andInformationTechnology254-84.*
[80] *S and Marper* v *United Kingdom,* ECtHR, Dec, 4, 2008

[81] Lee A. Bygrave, The Body as Data - Biobank Regulation via the Back Door of Data Protection Law, 2 Law Innovation & Tech. 1, 2010, p. 12
[82] Ibid, p.8

important to note that the Marper case provides good precedent for removal of innocent DNA from police records nothing extreme has changed only 377 people were removed from the database in 2009. [83]

4.2.3 The Nordic Countries

Finland is interesting to examine in their view to biobanking as the Nordic countries have been using biobanks to collect data for years. In Finland, policy innovation has become the main way to deal with the governance and development of biobanking. [84]

In 2006, Finland started drafting a new law with regards to biobanking aiming to infuse it in existing laws on the matter. The main issues the new laws want to tackle is the right of the sample donors, respect for the existing international agreements and supporting medical research in Finland. [85] Finland has also adjusted their legislation to cover research on archived biological material that is stored.

Finland has enacted a Biobank Act (Act 688/2012) that is in force since September 1, 2013. The Biobank Act was created to solve problems due to the overly strict informed consent doctrine and enable secondary uses of old samples and data.

Under the Biobank Act an individual should be informed about the owner of the biobank and about the biobank storing the samples and data. The registered field of activities of the biobank serves as a limitation for the use of its samples and data. In addition, the subject must be informed of the general nature of biobanking and its risks, the purposes of collection and storage, that this is a voluntary procedure, the right to cancel or limit the

[83] As revealed by Home Office minister Alan Campbell in January 2010: **http://www.telegraph.co.uk/news/newstopics/politics/lawandorder/6990617/Just-one-innocent-DNA-profile-removed-by-police-from-national-database-every-day.html**, Telegraph, Jan. 14, 2010

[84] Pitkanen K, Hassinen S. Opportunities becoming reality. Kemia-Kemi (2007) 34(5):32–3

[85] Aaro Tupasela, Sinikka Sihvo, Karoliina Snell, Piia Jalinoja, Arja R. Aro & Elina Hemminki, Attitudes towards biomedical use of tissue sample collections, consent and biobanks among Finns, Scandinavian Journal of Public Health, 2010; 38: 46–52

consent at any time. The subject also has the right to give consent to their personal data being disclosed or linked to register data.[86]

A proposed idea by Finland, which was a step closer to dynamic consent, was creating a National Archive of Health Information (KanTa), which is currently being developed to serve health care, pharmacies and citizens. The services, once fully operational, would include electronic prescription, a Pharmaceutical Database, a My Health Information, and a Patient Records Archive. With this database, a person could manage and access all his or her health data through KanTa, including biobank consent.

The Swedish Biobanks Act (2002:297), in effect as of January 1, 2003, clearly indicates that informed consent should be obtained for each new research project. Alongside this, the Swedish Ethical Review Act (2003:460), in effect as of January 1, 2004, states that the research ethics committees (RECs) should strike a balance between the value of research and the risks of violation of privacy of the donor.[87] The RECs are then responsible to choose the consent procedures in accordance with legislation. When participating in a study in Sweden participants felt no need to be asked for informed consent in relation to new studies on their previously collected samples, provided that the studies were approved by the REC. [88]

Additionally, in the study it became clear that in Sweden tissue donors most prefer a general informed consent procedure where consent is asked in the beginning of the study only. The participants want the REC to use their power and decide on how to use the previously collected samples and allow storing the material as long as it is useful for further research. It is still important to note that in this study the preferences for information and consent always depended on the context, particularly the risks of the donor and the purpose of the research.

[86] Sirpa Soini, Finland on a road towards a modern legal biobanking infrastructure, European Journal of Health Law 2013(3) 289-94, online: http://www.brill.com/european-journal-health-law
[87] Asa Kettis-Linblad, Lena Ring, Eva Viberth & Mats G. Hansson, Perceptions of potential donors in the Swedish public towards information and consent procedures in relation to use of human tissue samples in biobanks: A population-based study, Scandinavian Journal of Public Health, 2007; 35: 148–156
[88] Ibidem

The Swedish national biobanking program has established regional biobank registries that act as contact points for withdrawal of consent for all biobanks established within defined geographical regions.

In Norway, the research use of both personal health data and samples is regulated by the same legislative instrument: The Health Research Act, Helseforskningsloven, hereafter the HRA. [89] This legislation covers specific provisions human biological material and requires the storage and processing of material in research biobanks to be carried out in accordance with the donor's requests. Patients should be informed that their biological material is being used for research and they are provided a right to withdraw this right. Additionally, there is an electronic register in place with patients who have stated that they do not want their biological material used for research purposes as seen in § 28 of the HRA. Under §12 of the act unless specific legal authority or another valid legal basis exists, the collection, storage, and processing of human biological material and data for research purposes require consent by the donor, which should be (1) voluntary, (2) express, and (3) informed. Additional consent must be obtained if the biological data will be used for wider scope or different novel use then originally specified.

It is important to note that explicit consent is not necessary needed to be received for research purposes if the specific conditions laid out in the HRA are met as stated in §35.[90] The REC may decide that such data can be handed over by health personnel for use in research if, and only if, the research in question is of significant interest to society and the data subject's welfare and integrity are ensured. Importantly, when it is impossible or difficult to gain new consent the REC can grant an exemption from the requirement according to §15 of the HRA. It is crucial that the REC still specify he new or changed use of the research material. In addition to this, §20 stresses that anonymized material does not

89 The Health Research Act 2008 (Helseforskningsloven), https://app.uio.no/ub/ujur/oversatte-lover/data/lov-20080620-044-eng.pdf Accessed March 30, 2020

90 Jane Kaye et al, Consent for Biobanking: Legal Frameworks of Countries in the BioSHaRE-EU Project, Biopreservation and Biobanking Volume 14, Number 3, 2016 Mary Ann Liebert, Inc.

require consent. With regard to withdraw of consent §11-13 state it is possible to withdraw consent at any time. The person can request any health and personal data to be erased, destroyed or returned unless the material was anonymized or is actively being used for scientific work.

As we can see there are different sources of law used in each jurisdiction. This remains so because there is no single European legislative instrument that regulates human tissues in research or biomedical research as a whole. This means that each MS has a wide range of national laws that apply to human tissue research. Some countries have a united front for instance inland and Norway have implemented law that merges consent requirements for data and samples.[91]

4.3 Self Determination and Biobanking For Research Purposes

4.3.1 OECD Guidelines on Human Biobanking and Genetic Research Databases

The OECD Guidelines on Human Biobanks and Genetic Research Databases (HBGRD) provides guidance for the establishment, governance, management, operation, access, use, and discontinuation of human biobanks and genetic research databases, which are structured resources that can be used for the purpose of genetic research on human biological material.

The HBGRD aims to foster research and should be governed in accordance with legal frameworks. They should make data and materials readily available to researchers to advance studies and understanding. The organization is responsible to ensure development and maintenance of clearly documented operating procedures and policies for the procurement, collection, labelling, registration, processing, storage, tracking, retrieval, transfer, use and destruction of human biological materials, data and/ or information.

The HBGRD is of high importance in biobanking not just for its storage but also for the consent procedures. They are responsible for the review process in accordance with applicable law, this includes research ethics committees and oversight mechanism with regard to biological materials within the consent process. They are responsible to review

[91] Ibid

the following when biological materials are not used in a way that was originally specified in the original consent agreement:

- for previously collected human biological materials or data where the use might deviate from the original consent;
- for cases where informed consent may not have been obtained at the time of collection;
- for determining when to seek re-consent;
- for use of human biological materials or data where consent was obtained using a broader or layered format for uses unspecified at the time of collection, especially in the case of large-scale genetic epidemiology studies. [92]

The HBGRD stays neutral in the process of evaluation and works transparently. They help in consent procedure evaluations by ensuring that participants of studies have access to updates regarding the type of research they are participating in and what data is stored in their database. They individuals involved in the oversight process usually have a diverse area of expertise in regard to the materials being observed. Prior consent must always be obtained from each participant. "The HBGRD may provide for obtaining consent/authorization from an appropriate substitute decision-maker, or for obtaining waiver of consent from a research ethics committee or an appropriate authority, in accordance with applicable law and ethical principles pertaining to the protection of human subjects." [93]

Additionally, the HBGRD is responsible on the protection of human biological materials and data. Before collecting of the human biological material, the operators of the database should make sure to provide information on how the materials and data will be protected to all participants. The collection of such data should also be conducted in a way that protects patients' privacy and confidentiality of the sample material and the data. According to the HBGRD principles human biological materials should not be transferred to other parties to safeguard privacy and confidentiality of participants. In addition to this, researchers should

[92] OECD Guidelines on Human Biobanks and Genetic Research Databases, European Journal of Health Law 17 (2010) 191-204
[93] Ibidem

only gain access to the human biological material in a coded and anonymized fashion so that the participant cannot be identified.

With regard to withdrawing material from the HBGRD it is possible to do so. The HBGRD is responsible to dispose or transfer the biological material to the necessary entity with high regard to privacy and confidentiality.

The HBGRD, if implemented properly, is a good way to maintain the privacy and confidentiality of biological materials of participants and at the same time foster research. The HBGRD provides safe consent mechanisms as well as opting out process for participants. If laid out clearly to the donors of the material this has a lot of potential to prevent abuse of privacy, as well as cluing in the participant into their rights. This demonstrates a huge step in involving the donors in the process. I believe the HBGRD has a good set of mechanisms in place in terms of data protection and governance on how to treat human biological material properly. The HBGRD can provide quality assistance to biobanks that need to do extra research on biological materials in a safe and reliable manner. The organization also fosters research and opens the door for researchers to help in studying certain issues in the medical world and can in the long run help biobanks yield high results in their research.

4.3.2 Academic freedom in biobank research

Angry public reaction to scandals involving human tissue and organs without consent, concerns with biobanks and other tissue-related controversies, is often used to justify the claim that the public doesn't trust biobanking researchers.[94] On the other hand, people generally have high levels of trust in health professionals and medical research bodies that their interests will be protected. [95] Empirical studies of biobanking have shown high levels of public trust with risks seeming to be well managed through existing regulatory systems.

[94] Hansson M, "Building on Relationships of Trust in Biobank Research" (2005) 31 J Med Ethics 415
[95] Levitt M and Weldon S, "A Well Placed Trust? Public Perceptions of the Governance of DNA Databases" (2005) 15 Crit Publ Health 311

[96] With trust being on the rise toward biobanks it is essential to examine what level of academic freedom there is in clinical research as a whole. What are university biobanks rights to research and how much academic freedom do they have.

University biobank projects usually began just as any other research project with an idea created by a researcher to pursue their interest. Other biobanks have some extra skin in the game with scientific value that goes beyond the project initially planned only for collecting and sampling data. Some examples of such projects may include how unique samples are, finding the samples linked in disease registries, or even that a sample could be used to explore a cure for a rare disease. Universities participating in such studies are valuable and should be adopting policies to deal with the research being done in the biobanks. The policies should cater to ensure freedom in individual freedoms of researchers and still protect the privacy and basic values of a biobank. This can be hard to balance but will be analyzed and discussed, nonetheless.

Universities perform a lot of research on a daily basis and thus become a site where data is stored and collected overtime. Now universities even store resources in biobanks. Biobanks are important in biomedical research and often contain many samples of human biological materials such as tissues. University staff usually runs biobanks at the university and there is a lot of discrepancies sometimes on how to manage the stored data and materials. There are also challenges that arise when sharing data in international research collaboration as legal procedures vary from country to country on protecting donor rights. [97] It is interesting to note that although there has been a lot of biobank at universities, the institutions are not showing a high level of interest in developing national or international standards to sustain the biobanks better in the long run, which is a big challenge to harmonization of such institutions. [98]

[96] Lipworth W, Morrell B, Irvine R, Kerridge I. An empirical reappraisal of public trust in biobanking research: rethinking restrictive consent requirements. J Law and Med. 2009; 17:119-132]

[97] Keogh B. European Biobanks forge cross-border ties. J Natl Cancer Inst (2011) 103:1429–1431

[98] Kongsholm et al, Challenges for Sustainability of University-run Biobanks, Biopreservation and Biobanking, (2018), 16:4

The universities do not fall outside the scope of any other biobank standards they must respect the rights and privacy of donors, which comes with a significant amount of legal obligations. The important step to take is to make sure that informed consent was received from the donor. The institution that receives the sample should have a place for storage of the materials or data and the recipient or any information leading to their identity must not be named in any publications. [99] Compliance is essential now with the GDPR in place.

The GDPR has mandated that personal data should be processed transparently, fairly, and lawfully. This new EU legislation deems consent not only a requirement but forces data to be processed according to the standards lied on in the regulation for it to be a lawful activity. According to the GDPR researchers that handle human data are bound to remove personal data collected by them if the data subject requests their personal data be removed. The only exception to this case is if the information gathered is processed for public interest.

The GDPR also stipulates the right to erasure. The right to erasure basically states that when personal data can be erased upon request. According to Article 17 of the regulation this may apply in cases when materials are no longer necessary for the purpose of research, were not processed lawfully or the subject of the study withdraws their consent for further use of their biological materials. However, if the data being processed or archived it for public interest research then the right of erasure cannot be applied if it is "likely to impair the achievement of the objectives' of that processing."[100] University biobanks should carefully study the new requirements set forth in the GDPR and have proper guidelines in place because ramifications can be quite strict and can impact further research within the biobanks.

University biobanks are not just limited to the GDPR they are often also getting some sort of economic assets from running of the biobank. This means that they can make a profit from their research by protecting research results through patents, trade secrets, and protect their databases. Universities using biobanks for such purposes must follow the principles laid out in EU Recommendation CM/Rec (2016) 6, which enshrines the principles of

[99] Ibidem
[100] GDPR Art. 89

governance when obtaining, storing, or using biological materials along with interoperability of data for research purposes. If the university-based biobank follows this structure they must clarify the share of ownership of intellectual property bred within the framework of the biobank-based projects. In this work model there could also be the serious issues that need to be addressed with regard to cross- border exchange of samples and data transfers, which is an increasing problem within the EU harmonization of current biobank processes. [101]

Universities are required, to take measures to implement the principles set out under the Code of Practice annexed to Commission Recommendation C (2008) 1329 on the management of intellectual property in knowledge transfer activities. [102] The Code recognizes institutional ownership over ownership rights previously held by academic employees, commonly known as 'professor's privilege', as the default legal regime. [103] This means that university-run biobanks should clarify the distribution of ownership of the focal point intellectual property discovered in the biobank-based project. According to Article 3 of EC Directive 98/44/EC (Biotech Directive), inventions satisfying the basic patentability criteria–that is novelty, inventive step, and industrial applicability–are considered patentable even if they involve a product consisting of, or containing, biological material. Additionally, Article 5 solidifies that this principle extends to human biological material if it has been isolated from the human body or otherwise produced through technical means that has been unveiled in a patent application.

Besides patent law, database rights may be applicable in university run biobanks. The GDPR includes specific rules on protection of databases, providing exclusivity for databases encompassing genomic information. This type of ownership of data/information will cause tension between stakeholders by having multiple groups of researchers that have

101 Goebel JW, Pickardt T, Bedau M, Fuchs M et.al. Legal and ethical consequences of international biobanking from a national perspective: the German BMB-EUCoop project. *European Journal of Human Genetics* (2010) Vol. 18, No. 5, pp. 522-525

102 Commission Recommendation on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations, C (2008)1329 online: http://ec.europa.eu/invest-in-research/pdf/ip_recommendation_en.pdf. Accessed Sept. 6, 2018.

103 Kongsholm et al, Challenges for Sustainability of University-run Biobanks, Biopreservation and Biobanking, (2018), 16:4

ownership rights. Put simply, database rights may point toward the university, the funder, or the researcher, as the beneficial owner. If the university follows such a model, then there must be proper management of intellectual property in place between all the collaborators involved. However, it is much more beneficial for university researchers and biobanks to collaborate generate and analyze data collectively, rather than protect their own high-quality data separately. If proper management of IP is set in place and clearly arranged collaboration will be successful.

With regard to freedom for research the GDPR ensures sufficient flexibility and reconciles data protection principles and research, which has wiggle room for the MS to maneuver domestic legislation. Article 89(1) and 89(2) of the regulation allows for the processing of data for research purposes with appropriate safeguards, particularly MS should lay down specific safeguards for personal data that has been stored for longer periods of time than anticipated originally when used for scientific research. [104] This discretion allows each MS to find a perfect balance between protecting the individuals and safeguarding scientific research in obtaining their public health goals.

One last factor to consider is the financial burden. When a university is trying to run a biobank, they could come upon financial challenges in long-term sustainability of such projects. Biobanks often need an extensive business plan and investment strategy. [105] Usually network grants and research grants will not cut the cake to fully sustain a university biobank. The suggested solution to such a problem is that biobanks should be embedded with healthcare structures so that they can be used not only for research but also clinical purposes. [106]

With all this in mind, universities have to decide for themselves the extent to which they want to become commercialized and will have to monitor the effect the commercialization

[104] Article 89(1) GDPR
[105] Vaught J, Rogers J, Carolin T, Compton C. Biobankonomics: developing a sustainable business model approach for the formation of a human tissue biobank. *J Natl Cancer Inst Monogr*. (2011) Vol. 2011, No. 42, pp.24-31.
[106] See further: Murtagh MJ, Demir I, Harris JR, Burton P. Realizing the promise of population biobanks: a new model for translation, *Human Genetics (*2011) Vol. 130

has on their research, public confidence in research, and academic freedom.[107] Universities should re-examine every aspect of their contracts with industry, how to prevent dangerous relationships between faculty members and industry, and how to evolve standards for research practice to ensure protection of their scientific researchers if difficulties come about. Universities should have a clear understanding with the research facilities, biobanks and hospitals the partner with on the standing of laboratory specialists.

4.3.3 Ethical research and analysis in biobanking

Informed consent is codified in international settings in the Helsinki Declaration and Nuremberg Code. Respecting the autonomy of research subjects and their right to refuse to participate in research does stretch out through long spans of history in the research field.[108] The concept of donors as independent agents is a key concept in research nowadays, thus identifying what information and freedom is necessary before a person can make an autonomous decision is inherent to all forms of biobanking and genomic research linked with human or biological specimen.

Different consent methods have been discussed, but in practice biobank forms would need to obtain broad, specific or presumed. With the changing methods and updates necessary in biobanking, the suggested method seems to be dynamic, as it compromises between the specific and broad terms of consent. Large biobanks that are in action deem that broad consent is the most favorable despite the fact that there is still a debate among ethicists whether protects the autonomy and free will of the donors.[109] With consent models it seems that there will be no one method that is the ideal and in consensus with reciprocity, anonymity and the right to know. Thus, it is important that researchers should plan and conduct their research according to what the donors would expect when consenting to donating their samples.

[107] Somerville MA. A postmodern moral tale: the ethics of research relationships. Nat Rev Drug Discov (2002) 1:316-20.
[108] Vollmann J, Winau R. Informed consent in human experimentation before the Nuremberg code. BMJ 1996;313:1445–7.
[109] Petrini C. 'Broad' consent, exceptions to consent and the question of using biological samples for research purposes different from the initial collection purpose. Soc Sci Med 2010;70:217–20

While data protection is important for protecting individual rights, it is not always the same as participant protection in the research field. This fact is exactly why research ethics committees are often involved in decision making and need to carefully weigh each individual research project using biobanks. In some cases, this could mean that the autonomy of researchers may outweigh the free will of the participants as the research may be necessary to promote health or prevent potential harm to the greater society. With data protection being a crucial issue with regard to biospecimen it is important that biobank projects carefully explain their reasoning for resorting to certain levels of anonymity and to always ensure proper consent is gained. Ethics committee members should take an active role in understanding data protection laws with regard to samples and data, they should have active trainings on how to properly evaluate risk factors on privacy of donors in each specific biobank project.

"In Finland, biobank-related research is subject to specific legislation according to which primary collection of biobank materials and secondary use of data derived from those materials are subject to medical research law and ethical review or equivalent evaluation provided in that law. Data protection law is applied in a supplementary way to the processing of personal data relating to the materials in the biobank. In addition, the relevant provisions of the Finnish FoIA with regard to secrecy of personal health and social security information are applied to accessing data from biobanks."[110]

4.3.4 Genetic databases and biobanking: access to genetic privacy rights

Biobanks create a challenge revolving around the autonomy of an individual. Storing tissue and DNA samples for long periods of time coupled with the possibility to create endless DNA copies from a single sample, cause concern that these samples could be used for purposes other than those for which they were originally intended.[111] If unauthorized by the individual such as use of the sample will require additional consent from the subject.

The European society of Human Genetics suggests that anonymous samples can be used for purposes other than originally specified, so long as the samples are irretrievable and the

[110] Marjut Salokannel , Ethical Review, Data Protection and Biomedical Research in the Nordic Countries: a Legal Perspective, Policy Paper 1/2017

[111] George J. Annas, *Genetic Privacy: There Ought to be a Law, 4* TEXAS REV. L. & POL. 9, (1999), p.13-14

name of the donor is not released.[112] In addition to this, the UK Human Genetics Commission condones conducting research on old samples obtained without informed consent if the samples were anonymized. [113] An alternative to this that biobanks are using is asking open-ended permission to use their genetic information in future studies. [114] This is a weak form of consent because the research subject in this case will not be updated on where their materials are tested and for what purpose. This is a big privacy concern as then the subject loses rights and control over their biological material.

With the rise of technology there has been increased privacy concerns as mega databases can hold immense amounts of information nowadays, and these databases can contain biological information that is not new. On the flipside with finding ways to protect genetic, biological and medical information has been on the rise. The creation of biobanks has facilitated scientific progress, for instance being useful when it comes to tissues collected being stored in databases adding value to healthcare systems and pharmaceuticals, [115]but they also added new privacy concerns in the mix.

These new technological developments have led the private sector to become increasingly involved in collecting, assembling, and linking genetic information, through partnerships with government or research institutions that willingly transfer individuals' genetic material and/or information to the hands of the private sector. [116] This can be a problem since the private sector is only interested in making money, they have no interest in protecting the public interest. Therefore, there is a danger of these parties to not provide adequate enough

[112] Recommendations of the European Society of Human Genetics, *Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues, 11* Eur. J. Hum. Genetics S8, S9 (2003)
[113] Human Genetics Commission, Inside Information: Balancing Interests in the Use of Personal Genetic Data, *(*2002), online: http://webarchive.nationalarchives.gov.uk/20081023100824/http://www.hgc.gov.uk/UploadDocs/DocPub/Document/insideinformation_summary.pdf
[114] Yael Bregman-Eschet, Genetic Databases and Biobanks: Who Controls Our Genetic Privacy, 23 Santa Clara High Tech. L.J. 1 (2006). Available at: http://digitalcommons.law.scu.edu/chtlj/vol23/iss1/1
[115] Graham Lewis, *Tissue Collection andthe PharmaceuticalIndustry: Investigating CorporateBiobanks, in* Genetic Databases: Socio-Ethical issues in the collection and use of DNA 181, p. 182-186, Richard Tutton & Oonagh Corrigan eds. (2004)
[116] Daniel J. Solove**,** The digital person: technology and privacy in the information age, (New York University Press 2004), p. 13-21

safeguards to ensure the subjects privacy. The private sector can misuse the sensitive information simply to make some extra money.

There is an important need to focus on the fact that there is a lack of restrictions and guidelines on private companies on storage of genetic information. Private companies are free to choose how much security and what due care steps they take to ensure that the sensitive data does not get out, and how they store and collect the information. With this there is a clear discrepancy in how sensitive information is stored and handled, which breaches privacy interests of the data subjects and creates confusion in conducting proper genetic research. [117]

The European Union allows personal information to be transferred only to nations that grant sufficient privacy protection measures. Limitations on transfers of genetic information include restrictions on the information's location, the receiving entity and future usages are required. [118] There is a definite need for extra scrutiny when it comes to sharing sensitive data with the private sector. Strict supervision must be implemented when partnering with for profit companies or third parties on research projects, particularly being careful when a partnership between private and public sectors is initiated.

The best suggestion in solving this problem is harmonization of the rights on storing and handling sensitive data. There should be a uniform rule on how private companies shall behave with such data. Adequate consent rights should be implemented with sensitive data. Lastly, there should be limitations or restrictions on compiling and using sensitive biological data.

[117] Yael Bregman-Eschet, Genetic Databases and Biobanks: Who Controls Our Genetic Privacy, 23 Santa Clara High Tech. L.J. 1 (2006). Available at: http://digitalcommons.law.scu.edu/chtlj/vol23/iss1/1

[118] *See further:* France Fukuama, *The Political Control of Biotechnology, in* Our Posthuman Future: Consequences of the Biotechnology Revolution 181, 181-94 (2002)

V Conclusion

5.1 Findings

Data portability increases informational self determination of the data subject. Data portability should provide the data subject with the control over the personal data.
It is no question that informational self determination is directly linked with information privacy. The data subject may determine to whom they disclose their personal data if at all. Their decision on this matter should be made freely without any undue influence from a third party for informational self determination is preserved. Nonetheless, the right to data portability, provides a means for providers to attract users with even more personalized services. These developments can result in lax rules on privacy protection of informational privacy of the data subjects for various reasons, whether to make profit or to promote research.

For our purposes it is important to note that the right to data portability only applied to personal data. Therefore, this leads to the idea that data portability does not apply to anonymous data.[119] Yet, pseudonymous data that can clearly be linked to a specific individual is still within the scope of this right. Notably, the GDPR does not specify how individuals should make data portability requests. Therefore, requests could be made verbally or in writing. A request does not need to include the phrase 'request for data portability' nor does it need any reference to Article 20 of the GDPR.

While the GDPR provides the option of data portability there are exemptions for biobanks from a number of GDPR principles and data subject rights if and when the personal data is being processed for scientific research.

Informational self determination can be viewed as a proprietary right to personal data. Data portability is the transfer of an object, taken from one place to another and handed over, in our case the data transfer is the data subjects personal data. Data portability as proposed in the General Data Protection Regulation as two relatively separate rights, the right to obtain

[119] Article 29 Data Protection Working Party, Guideline on the right to data portability, online: http://ec.europa.eu/information_society/newsroom/image/document/2016-51/wp242_en_40852.pdf

a copy from the controller and the right to data transfer.[120] Even though, these rights enhance informational self determination, they do not guarantee full control over personal data, as there is even differentiation on when the data portability can be extended based on the necessity of the material gathered from the data subject.

Consent for our purposes is an essential addition to the GDPR, particularly informed consent, which allows the individual to agree to data processing options and who gets access to their data. Privacy self-management allows people the right to take notice of how their personal data is being collected and used and need to decide whether or not they consent to such use of their data.

The right to withdraw consent was founded in The Declaration of Helsinki, The Nuremberg Code, CIOMS, as well as the Convention of human rights. It is also recently covered in the GDPR. The Declaration of Helsinki 1964 the demand for unrestricted individual rights to withdraw consent to participate in research is on the rise.

The Nuremberg Code saw research as a common good and idealized experimental subject as a greater good for humanitarian projects leading to different view on withdrawal rights[121], whereas the Helsinki Declaration provided the individual the right to withdraw regardless of the reasoning allowing for more freedom. The right to withdraw consent does not imply a right to withdraw results that have already accumulated, rather it implies that new data cannot be obtained, and that existing data must be maintained in an impersonalized form.

Although there was already the concept of individual rights in to stop participation in studies before in the Nuremberg Code of 1947, the Helsinki Declaration provided a clearer, easier way on how to do this.

The GDPR does not say that giving and withdrawing consent must always be done through the same action. The requirement of an easy withdrawal is described as a necessary aspect

[120] Eva Fialova, Data Portability and informational self-determinaton, Masaryk University Journal of Law and Technology, Vol. 8:1, 2014
[121] See further: The Nuremberg Code, 1947, BMJ 1996

of valid consent in the GDPR. If the withdrawal right does not meet the GDPR requirements, then the consent mechanism of the controller does not comply with the GDPR.

The GDPR has mandated that personal data should be processed transparently, fairly, and lawfully. This new EU legislation deems consent not only a requirement but forces data to be processed according to the standards lied on in the regulation for it to be a lawful activity. According to the GDPR researchers that handle human data are bound to remove personal data collected by them if the data subject requests their personal data be removed. The only exception to this case is if the information gathered is processed for public interest.

According to many regulations and guidelines, there is no need to destroy a sample when a participant withdraws from a study, since anonymization can solve the problem. Data protection in health research led to debates during the legislative process, in particular regarding whether there should be exemptions from the obligation to always seek consent before using patients' data for research in cases where asking for consent or re-consent is impossible (Article 89).

The argument for anonymization is linked to the fact that information derived from a participant's tissue cannot be used at their disadvantage if no one can find out their identity. The data subject does have the right to end participation in a study, but since it can be of importance to keep the sample for research, de-identification is the more preferred solution. Anonymization means that the participant is no longer participating; only the anonymous tissues are being observed, with no researchers gaining access to the identity of the donor. However, at the end of the day, ties from the donor still cannot be cut.

The HBGRD is of high importance in biobanking not just for its storage but also for the consent procedures. They are responsible for the review process in accordance with applicable law, this includes research ethics committees and oversight mechanism with regard to biological materials within the consent process.

The HBGRD is responsible on the protection of human biological materials and data. Before collecting of the human biological material, the operators of the database should make sure to provide information on how the materials and data will be protected to all participants. The collection of such data should also be conducted in a way that protects patients' privacy and confidentiality of the sample material and the data. According to the HBGRD principles human biological materials should not be transferred to other parties to safeguard privacy and confidentiality of participants. In addition to this researchers should only gain access to the human biological material in a coded and anonymized fashion so that the participant cannot be identified.

5.2 Recommendations/Commentary

With regards to consent models I think that the most appropriate form of consent in biobanking is dynamic consent. Dynamic consent allows for constant communication with the tissue donors and for them to change their preferences allowing them to be in control of where their materials go and to what study. The fact that the dynamic consent model informs research participants about the research they are involved in is essential in all types of research consent processes. This method better distributes detailed information compared with broad consent. Additionally, dynamic consent increases trust and willingness to participate in research. The aim of dynamic consent is to be more inclusive compared with regimens utilizing broad consent.

This method of consent is also more applicable with the GDPR as it provides a specific and informed explanation of where the sample will be used and for what purposes. On the other hand, dynamic consent seems to go against Article 9(2) with regards to sensitive data, but I think that this is a good thing as it is an infringement of fundamental rights.

From my research I am of the opinion that privacy law often relies too much on privacy self-management. Privacy self-management cannot achieve privacy alone. Many privacy issues are inherently linked with the consent dilemma. A coherent approach to consent must be developed in legal framework, taking into account how individuals actually make decisions about their personal data. It is also important to develop more substantial privacy rules and timing necessary for consent. While, an individual can take part in privacy self-

management it is important to remember that individuals can often only participate in this selectively and if they fully understand what they are consenting to.

One of the biggest dilemmas in data protection of personal data has been finding a balance between informational self-determination and an individual's control over their data with the competing interest of the one's collecting, using and processing their data. Yet, in my research I determined that the right of informational self-determination prevents enterprises or government agencies from doing whatever they want with the data of private citizens. This legislation guarantees the fundamental right of individuals to determine whether and how their data should be used or released.

As biobanks process 'personal data', European data protection law applies in their day-to-day operations. Despite the clear evidence that data protection law applies, there remains uncertainty about the exact application of the General Data Protection Regulation. There are questions if open consent is legitimate is one such uncertainty. On top of this there is a wide range of opinions on what types of consent is applicable in the use of sensitive data. In addition to this, the GDPR requires that any consent be 'specific' and 'informed'. This could pose a problem for biobanks operating with open consent as they cannot meet these requirements.

According to extensive research most ethical guidelines are for the protection of withdrawal of consent in biobank research. However, there are no explicit explanations as to why this should be an available remedy within these documents. Invoking the right to withdraw consent is important for the public to have trust in researchers and will promote more participants if they know they have an option to opt-out or remain in the biobank research process.

Anonymization is often the go-to solution for protecting privacy in biobanking but it should not be the default setting of from researchers and biobank holders when requests of withdrawal occur. On the other hand, a request for withdrawal should not stop research on identifiable samples. Instead of the present emphasis on individuals' right to withdraw consent to research on their biological samples for any reason, the clause on withdrawal in

the Nuremberg Code be included in guidelines on biobank research.[122] This would allow anonymization as a solution to the withdrawal of samples and promote further research on the tissue in question. Although there would also have to be reforms on researchers requests of the samples and a way to ensure that the information of the donor doesn't get released through medical journals.

The HBGRD if implemented properly is a good way to maintain the privacy and confidentiality of biological materials of participants and at the same time foster research. The HBGRD provides safe consent mechanisms as well as opting out process for participants. If laid out clearly to the donors of the material this has a lot of potential to prevent abuse of privacy, as well as cluing in the participant into their rights. This demonstrates a huge step in involving the donors in the process. I believe the HBGRD has a good set of mechanisms in place in terms of data protection and governance on how to treat human biological material properly. The HBGRD can provide quality assistance to biobanks that need to do extra research on biological materials in a safe and reliable manner. The organization also fosters research and opens the door for researchers to help in studying certain issues in the medical world and can in the long run help biobanks yield high results in their research.

Universities have to decide for themselves the extent to which they want to become commercialized and will have to monitor the effect the commercialization has on their research, public confidence in research, and academic freedom.[123] Universities should re-examine every aspect of their contracts with industry, how to prevent dangerous relationships between faculty members and industry, and how to evolve standards for research practice to ensure protection of their scientific researchers if difficulties come about. Universities should have a clear understanding with the research facilities, biobanks and hospitals the partner with on the standing of laboratory specialists.

Open-ended permission to use their genetic information in future studies is a weak form of consent because the research subject in this case will not be updated on where their

[122] Ibid
[123] Somerville MA. A postmodern moral tale: the ethics of research relationships. Nat Rev Drug Discov (2002) 1:316-20.

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[124] *See further:* France Fukuama, *The Political Control of Biotechnology, in* Our Posthuman Future: Consequences of the Biotechnology Revolution 181, 181-94 (2002)