Anonymisation and Pseudonymisation as Means of Privacy Protection

Second International Workshop of the Tiss.EU Project

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1 Introduction

The second international workshop within the Tiss.EU project was organized by *Judit Sándor* and *Petra Bárd* from the Centre for Ethics and Law in Biomedicine (CELAB) at the Central European University (CEU), Budapest, Hungary. It focussed on one of the four Focal Themes of the Tiss.EU project by addressing questions of "Anonymisation and Pseudonymisation as Means of Privacy Protection" (Focal Theme C) in relatively unexplored jurisdictions of Central and Eastern Europe such as the Czech Republic, Hungary, Slovakia and Romania. Due to the interdisciplinary nature of the workshop's subject, invited speakers represented a wide range of disciplines such as law, medicine, philosophy and information technology.

The structure of the workshop followed a two-track approach: on the one hand speakers presented their countries' regulatory framework and existing practices concerning anonymisation, and on the other scholars addressed various related theoretical concerns and problems. Emphasis was put on the geographical

scope of the workshop: invited were not only experts to summarize the related legal rules in their own countries, but also scholars from Central Eastern European jurisdictions to address the theoretical issues.

The substantive part of the workshop started with general presentations framing the issue of anonymisation and pseudonymisation.

As a first speaker, *Christian Lenk* as representative of the coordinating institution University Medical Center Goettingen greeted the audience and emphasized the special importance of personal data and genetic data in ethics and law in his introductory remarks. In particular, he asked whether common standards of anonymisation in medical research can be obtained and how the privacy of and control over medical data can be secured.

Judit Sándor, CEU professor and Director of CELAB, representing the host institution of the workshop, gave a thorough analysis mapping anonymity issues. She made reference to different areas of life and illustrated her point on the importance and diverse nature of anonymity with examples from different branches of law. She also drew attention to a perceived relation between anonymity and altruism: according to this view, the ultimate form of altruism is the total absence of a personal relationship, like in the case of an organ donation between complete strangers, where the identity of the donor and recipient is hidden through anonymisation. In the special case of biobanks, however, she was sceptical as to whether altruism can be presumed on the side of the gene donor, especially since biobanks are combinations of research and commercial enterprises. Sándor also emphasized the divergent functions and the lack of a uniform definition of anonymisation in both international instruments as well as Hungarian pieces of legislation.

The keynote speech, delivered by *Bernice S. Elger*, professor at the University of Geneva, Switzerland, went into the clashing interests, the importance of biobanking and that of privacy protection. According to her, the ethical and legal framework for genetic research with human tissue is currently not well defined. In particular, she stressed that terminology varies widely concerning different degrees of anonymisation. The exact definition and understanding of anonymisation is important for sample donors, researchers and ethics commissions for several reasons: it not only informs about the degree of protection and risks to confidentiality, but in most jurisdictions, it also influences the type of required consent to be obtained from sample donors. In the remainder of her presentation, Elger explored ethical, legal and practical problems related to anonymisation and pseudonymisation. In particular, she argued that complete anonymity is difficult to obtain, which leads to the predominant use of linked anonymisation. Following Elger, anonymization does still not mean that researchers are free of obligations to obtain consent. Rather, consent should be as specific as possible; only for future research (provided a Research Ethics Committee's approval) it might be acceptable to allow for general consent. In the end Elger strongly recommended to discuss the different regulatory frameworks at an international level in order to pave the way for a better harmonization of standards.

The second session opened with a presentation by *Ants Nõmper*, senior lecturer at the University of Tartu, Estonia, who presented his thoughts on autonomy by referring to the Estonian population databases. Estonia is of particular interest to researchers in the field of bioethics, and especially to those interested in biobanking. As Nomper pointed out, Estonia has provided controversial innovations in this field. Firstly, in 2000, it adopted a regulation on population biobanks that governed the usage of medical and genetic data and tissue samples of volunteers. Volunteers were asked to give an open consent that justified not only the collection of data and tissue samples but also an almost unlimited usage thereof in the future. In 2007, Estonia abandoned the consent requirement altogether and established its e-health project, in which participation is mandatory for each patient in Estonia, on the possibility of close access to data for third parties. Nomper's presentation also shed some light on the considerations behind both innovations and provided an update regarding the progress of these projects. He concluded his presentation by suggesting that autonomy could be enhanced by better access control, more accurate data and a higher level of data protection.

Josef Kuře, Professor at the University Centre for Bioethics and Department of Medical Ethics, Masaryk University in Brno, Czech Republic, talked about the ethics of biobanking. According to Kure, biobanking represents not only new possibilities in health care but also new challenges for governance framework(s) on the level of both, ethical reflection and legal regulation. In his presentation, starting with the informed consent concept and its application for various forms of biobanking, he provided a short overview of ethical aspects of biobanking. Amongst others, he argued that samples and data should be distinguished. Attention was also paid to concerns about some common research practices, including data availability, specific issues involving research without adequate consent, privacy, the commercialisation of biobank research and discrimination. In the end, Kure envisioned some possible future scenarios. The understanding and safeguarding of privacy and confidentiality may remain the same, or may be slightly altered in the future. Possible divergences may also take two directions: on the one hand we might move towards a strong privacy and confidentiality protection model, or towards abolishing privacy and confidentiality as we understand them today.

2 Country Reports: Slovakia, Czech Republic, Hungary, Romania

The first target jurisdiction to be addressed was Slovakia. Professor *Jan Koller* from the Central Tissue Bank, University Hospital Bratislava, addressed traceability requirements and privacy protection in Slovakian tissue and cell establishments. Starting his presentation with EU imperatives, Koller stated that since 2004, three European Directives (23/2004/EC, 17/2006/EC, 86/2006/EC) on setting standards of quality and safety for the donation, procurement, testing, processing, pre-

servation, storage and distribution of human tissues and cells have been adopted by the European Parliament and Council and the European Commission. In addition to safety and quality measures for human tissues and cells for use in humans, the Directives contain requirements on protection of human rights and privacy, assurance of confidentiality of any health related information, full traceability of donations and distribution of tissues and cells as well. The EU Member States have been obliged to implement the Directives into their national regulations (Slovakia did so at the end of 2007). The Competent Authority for tissues and cells in Slovakia is the Ministry of Health. The donation and transplantation system in the country is coordinated centrally by the Slovak Center for Organ Transplantations (SCOT). Since the beginning of 2009, a new centralized computer information system has been established in the country in order to assure confidentiality and privacy protection as well as full traceability of organs, tissues and cells and related products.

The SCOT uses a validated electronic system, the so-called Transplantation Information System Slovakia (TISS) presented by *Daniel Kuba* from the Slovak Centre for Organ Transplantation and professor at the Slovak Medical University Bratislava. Kuba first explained the organization and structure of the Transplant Network in Slovakia. The initial requirements for TISS at the development phase were accessibility through web application; the existence of a national central information system; organ procurement and transplantation data management; tissue and cells procurement, processing, storage, allocation and transplantation data management; the traceability and safety of recipients at the same time; whilst the legal requirement was the implementation of EU law and the adoption of relevant national pieces of laws. After giving an insight into the technical details of the system, Kuba continued by stressing the importance of safety for both, the hardware and basic software level. He emphasized that traceability and privacy protection are the most important issues of safety in the transplantation chain. Although these two requirements might seem contradictory, efforts should be made to harmonize them. In his view the new information system could become a tool through which these two requirements can be reconciled.

Lukáš Prudil, Associate Professor at the Department of Social Medicine and Health Care Administration, Masaryk University Brno, Czech Republic, presented a country analysis on the Czech Republic. Prudil addressed different aspects of human tissue and cell usage in the Czech Republic: in particular, he explained the legal background including its international aspects regarding the usage of tissues and cells for research purposes, usage of tissues and cells for purposes other than research (e.g. transplantation), research on human stem cells, creation of databases, and data protection issues. The Oviedo Convention, for example, has become part of the Czech Law by being incorporated into Act 96/2001. However, as Prudil explained, there is no unique legal document covering research and usage of human tissues and cells in the Czech Republic. Instead there is a diffuse legal regulation in this field due to a missing conceptual approach and an unreasonable divi-

sion of competencies among state bodies. To find a real legal regulation of this issue is thus like solving a puzzle. However, according to Prudil, the most probable legal solution is conformity with international obligations.

István Peták from the Hungarian Biotech Association, KPS Molecular Treatment Solutions and the Semmelweis Medical University presented the Hungarian country analysis, wherein he emphasized the importance of a uniform regulatory framework. Concerning the recent Hungarian legislation on human tissue research, Act No XXI of 2008 on the "Protection of human genetic data, human genetic tests and research and biobanks", which defines a biobank as a "collection of samples containing genetic samples and related genetic and personal identification data for the purposes of a human genetic study or human genetic research under this Act", is of major importance. According to Petak, however, a number of questions remain open, for example whether storage of biological material without DNA or RNA for research purposes satisfies the definition of a biobank, or whether informed consent for unforeseen research purposes is sufficient in a long-term perspective: can one ask for general consent, and if so, how general can the consent be, etc. Furthermore, he pointed to the review and authorisation practices by ethical committees, which can make up for the necessary and by nature incomplete donor consent. In Hungary, for non-invasive, non-interventional medical research studies either a local ethical committee or the Scientific and Research Ethics Committee (ETT-TUKEB) grants approval. The former decides on research projects done without genetic studies conducted by one single institute, whilst the latter decides if multiple institutes or registered biobanks are involved or if human genetic studies are carried out.

Zoltán Alexin, senior lecturer at the University of Szeged, Department of Software Engineering, addressed the specific topic of the workshop, anonymisation of health care data in Hungary. According to him, the essence of the private sphere is that no one can intrude into it against the data subject's will. If an unwanted intrusion takes place, this violates not only the right to privacy, but also the right to human dignity that includes the right to self-determination and the right to full bodily and personal integrity. Furthermore, Alexin underlined that Hungary is considerably late in implementing the internationally accepted ethical principles concerning medical research involving human subjects. An ethical review and approval for invasive research projects are legally obligatory since 2002; for non-invasive research since March 2007. However, as he pointed out, even today, some research is still done without ethical review. In fact, any ethically approved retrospective database research can be done without informing the participants and without obtaining their consent. Within this legal framework an expressly progressive step was made by the adoption of the Act on the protection of personal genetic data, on human genetic examinations, research and biobanks in 2008. In his presentation, Alexin also discussed some elements and deficiencies of the Hungarian legal system in connection with the ethical and data protection rulings. In particular, he criticized the current anonymisation methods by contending that neither the

American HIPAA guideline nor pseuonymisation provides a secure method to cease the connection between the data and the data subject. For this reason he pointed to a solution proposed by Johannes Gehrke (Cornell University), who advised a slight distortion of data, which would ensure the anonymity of the data subjects.

Ioana Berindan-Neagoe, Head of Functional Genomics Department, and Assistant Professor of Immunology from the Cancer Institute "Ion Chiricuta" Cluj Napoca Romania, addressed the issue of tumour banks and their use in functional genomic studies in Romania. She referred to Law no. 677 of November 2001 for the protection of individuals regarding the processing of personal data and free movement of such data as this moulds the background for the Romanian regulation concerning medicine and biomedicine and the international instruments ratified by the Romanian legislator. Neagoe also listed Romanian pieces of legislation covering the field of human tissue research. Decree no. 1242/2007, amongst others, deals with the approval of standards selection and the evaluation of donors' (healthy or diseased) tissues and cells. Decree 1763/2007 lays down the technical requirements for donation, sampling, testing, processing, preservation, distribution, coding etc. These provisions are transposing the Directives 17/2006/EC, 23/2004/EC, 86/2006/EC and 23/2004/EC into national law. The Romanian legislation makes sure that Romania participates in the establishment of a single European code, which will use a specific numerical code for identification of all human cells and tissues donated to the banks of cells and tissues, except for reproductive cells donated between partners. Neagoe emphasized that the obtainment of tissues and cells is considered a donation act that is regulated by certain ethical principles such as avoiding discrimination and securing people's confidence in research by assuring confidentiality to the patients.

Continuing with the Romanian jurisdiction, *Simona Zanfir*, counsellor at the Legal and Communication Department of the Romanian National Supervisory Authority for Personal Data Processing, addressed the question of the processing of personal data regarding the state of health and human medical research in Romania. The presentation focused on the general aspects concerning the legal framework for the processing of personal data in Romania, including certain information about the Romanian National Supervisory Authority for Personal Data Processing. The necessity of anonymisation was at the focus of her presentation. Due to the methodology of the National Institute for Statistics, confidentiality, access to medical data, security of data basis and the necessity of anonymisation related to human medical research were the main issues. Zanfir discussed the practical aspects of the processing of data regarding the state of health and human medical research in Romania before she derived her conclusions.

3 Results

Professor *Judit Sándor* and CELAB researcher *Petra Bárd* summarized the findings of the workshop. Recognizing the scale of the problem, they addressed two important issues in the field of anonymization and pseudonymisation: privacy concern and efficiency through standardization.

- All presentations – implicitly or directly – dealt with both issues: privacy on the one hand and the question of how anonymisation should be realized on the other hand, i.e. how to make the coding or pseudonymisation efficient enough so that researchers, donors, recipients and society in general can benefit.
- These issues, however, have to be preceded by a preliminary question: what is the goal of the given repository of genetic samples and data, i.e. what type of biobank are we dealing with? Theoretically, even in the absence of any information attached to a sample, the donor can be identified if a matching sample is taken from her/him. Therefore only (i) archaic samples, (ii) samples which underwent the pooling procedure or (iii) mathematically distorted data can be regarded as truly anonymous.
- Total anonymity is not only hardly conceivable or practical; it is not even desired in the diagnostics context. Donors may have compelling reasons to claim access to the tissues in the future. Therefore many jurisdictions have opted for allowing doctors and/or researchers access to the code (the Slovak model, for instance, seems to be in line with this proposal), whereas a number of scholars speak out for linkable anonymous samples where doctors do not have access to the code – a theoretical model that has been realised by the Romanian system.
- Anonymity requirements as laid down by Hungarian law are particularly interesting, firstly through the example of reproduction, but also in relation to the recently adopted law on biobanks. While the laws and definitions may be missing or contradictory, researchers, practitioners and scholars in the field seem to agree on the need for common ethical, legal and technical standards.

Peculiar characteristics of the national pieces of legislation in the target countries include the following:

- In the *Czech Republic*, extensive human subject research is executed, while a corresponding legal framework is missing. Rules applicable to biobanks, research conducted on cells and tissues, and anonymisation requirements cannot be found in a single legal document. There are however a number of general pieces of national legislation and international instruments governing the field.

- With regard to donation, there is a presumed refusal (i.e. a full written informed consent is required), except for deceased donors, in which case consent is assumed.
- Interestingly, according to the Act 227/2006, Ministry of Education approval (*not* Ministry of Health approval) is needed for stem cell research, which is a unique solution in Europe.
- In the Czech Republic, surplus embryos are still being created and may be used for research purposes, without being coded like other tissues and cells.
- *Hungary* had the first biotechnology association founded in 2002. The country has a solid record of attracting and conducting international clinical trials, with over 250 performed each year, which is outstanding especially if seen in light of Hungary's population.
- Since 2002 there has been an ongoing legislative process which resulted in the Parliamentary Act XXI of 2008 on the protection of human genetic data and the regulation of human genetic studies, research and biobanks.
- The law addresses the use of genetic information only in the very narrow biomedical sector: in the fields of genetic testing, screening and research. It restricts the use of genetic data only in this biomedical context; however, even given the lack of regulation on the broader use of genetic data, according to the Act XXI of 2008, data processed for diagnostic or research purposes cannot be disseminated for the purposes of insurance. The Act applies to genetic sampling for human genetic study and human genetic research performed under the Act on the territory of the Republic of Hungary, the processing of genetic data irrespective of the place of sampling, and to genetic testing and screening, human genetic research and biobanks.
- Genetic samples and data anonymised in accordance with the requirements of the Biobank Act even before its entry into force may be treated in line with the Act for human genetic research and study. One of the specificities of the Biobank Act is that it regulates three different levels of coding and anonymity: (i) encoded genetic sample or data, meaning the replacement of all personal identification data relating to the donor by a retained code; (ii) pseudonymous genetic sample or data, meaning encoded genetic samples or data that is provided to the person concerned together with the code replacing the personal identification data; (iii) anonymised genetic sample or data, meaning genetic sample or data where all personal identification data has been rendered inapt of identifying the person.
- For the purposes of human genetic research only anonymised, encoded or pseudonymised genetic samples or data may be transmitted to third coun-

tries, and only on the condition that the law of the given country provides for data protection corresponding to that under the Biobank and the Data Protection Acts. In the course of transmitting encoded genetic samples and data to third countries, the code key necessary for personal identification must not be relayed.

- For the purposes of human genetic study, only encoded genetic samples may be transmitted to third countries. Genetic samples or data may enter the territory of Hungary only from a third country where the requirements laid down in the Hungarian law are ensured; this has to be verified by the health authority.
- Review and authorisation by ethical committees can make up for the necessary yet naturally incomplete donor consent. In Hungary, for non-invasive, non-interventional medical research studies either a local ethical committee or the Scientific and Research Ethics Committee (ETT-TUKEB) grants approval. The former decides on research projects that do not include genetic studies and are conducted by one single institute, while the latter rules in cases where multiple institutes or registered biobanks are involved and human genetic studies are done.
- In *Slovakia* all European Union pieces of legislation have been transposed into national law.
- Concerning donation in line with the Health Care Act, the service provider uses a unique numerical code assigned to the donor and to all the products connected to him/her which is derived from the uniform coding system. The SCOT (Slovak Centre for Organ Transplantation) uses a validated electronic system, the so-called Transplantation Information System Slovakia (TISS).
- In *Romania*, tissue and cells sample collection is considered as a donation act that has to satisfy a number of requirements. Romanian law provides for a general prohibition to process particular categories of data, including data regarding the state of health, as well as for exceptions for processing special data.
- The National Supervisory Authority established in 2005 issues certain regulations on anonymisation, recommending the adoption of adequate security measures on a technical and organizational level. Accordingly, data controllers must evaluate the potential risks for data processing, establish adequate security policies, inform and permanently train the employees, and establish the control on access to avoid unauthorised access from administrative personnel or anyone else.

Judging from the workshop's presentations on the regulation of human tissue research in the Eastern European countries, at least some common tendencies can be derived:

- All national legislations refer to the Oviedo Convention on Human Rights and Biomedicine.
- International standards are considered far more important than in many long-time Member States of the Council of Europe.

Despite the fact that all national legislations refer to the Oviedo Convention and adhere to European Union standards, Member States of this particular country group (Hungary being an exception) do not seem to take the lead upon their own initiative to go beyond the European minimum standards.