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Studying the ethical, legal and social aspects of biobanking

The last few years have witnessed an important expansion of collection and processing of human biological samples and of the related information data. Biobanks are huge repositories of human biological specimens and have a strategic importance for genetic research, clinical care and future treatments. Therefore GeneBanC aims to investigate the ethical, legal and social issues of three types of biobanks: classical banking, population banking and forensic DNA databases.

Privacy and confidentiality

The first objective of the research project is to study the issue of privacy and confidentiality. There are reasons to believe that an unquestioned transfer of the traditional concept of confidentiality to the three types of biobanking described may be problematic, and that the concept needs to be re-analysed in these new contexts.

DNA and crime

The third objective is to investigate the ethical and policy issues related to forensic databases. In a post 9/11 era forensic genetic databases (i.e. for the prevention of crime, terrorism) generate many questions that have had no attention until now on a European level.

Governance

The fourth objective is to investigate governance aspects of biobanks. The objective is to study the social, ethical, scientific-technological, and political-regulatory embedding of biobanks, to help the understanding of the ethical, socio-economic, scientific-technological and political implications of biobank development on the local and the national level, and in the transnational field and thereby to contribute to a better understanding of biobank governance.



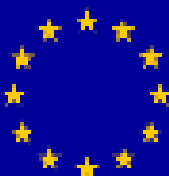
The results obtained within the different objectives described above will be of great use for the development of policy oriented recommendations concerning the organisation and management of small scale biobanks, population databanks and forensic DNA databases. Also, we aim to make proposals in order to reach where appropriate a harmonized regulatory framework across the European Union.

Laws

The second objective is to investigate the existing regulatory framework of biobanks across the EU and to focus on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks. The analysis of existing legislation will also provide some suggestions for “best rules”.

regulatory framework across the European Union.

GeneBanC is an acronym for *Genetic bio and dataBanking: Confidentiality and protection of data. Towards a European harmonization and policy*. It is a Specific Targeted Research Project (STREP) funded by the European Commission in the Sixth Framework Programme. The project number is FP6-036-751.





“The Section for Medical Ethics is also involved in another international research-project on genetic data and biobanking”



“We will conduct interviews with the scientists responsible for biobanks and registers”

Confidentiality and privacy in biobanking

The first workpackage in the GeneBanC is coordinated by Jan Helge Solbakk, the head of the Section for Medical Ethics (SME) at the University of Oslo. This workpackage wants to analyse the concept of confidentiality in relation to two types of biobanks (small scale and population based), to analyze what the implications of confidentiality are in biobanks with multiple uses, and in biobanks that have changed use since their establishment. In addition, it wants to analyze the links between confidentiality and a more general right on the part of tissue or DNA donors to control their sample or information (e.g. as an expression of their right to self-determination) and the links between confidentiality and a more general right on the part of tissue or DNA donors to privacy. Finally, it wants to analyze the meaning of confidentiality in relation to donors who are dead or untraceable. To realize these objectives, this unit will perform a comprehensive review of the literature on medical confidentiality with a special focus on confidentiality in research and with regard to databases and biobanks. This review aims to provide a typology of the justifications of confidentiality; a typology of the scope of



confidentiality and a typology of possible exceptions to confidentiality. A qualitative study is also planned. The researcher Jan Reinert Karlsson will work on the project. Currently SME is also involved in another international research-project on genetic data and biobanking sponsored by the Norwegian Research Council. (Mapping the language of health biobanks and health registries - From traditional biobanking to research biobanking.) This project is pursued in partnership with the Norwegian Public Health Institute which is responsible for the largest Norwegian biobanks, and counts partners in France and Portugal.

Population and small scale biobanks

Darren Shickle is professor of Public Health at the Institute of Health Sciences and Public Health Research (University of Leeds). He has previously conducted consultations for UK Biobank with both the general public and health professionals. He is also a member of the Executive Committee for the Fosse Way Cohort, which is the largest of the Regional Collection Centres for UK Biobank. He is also member of the Airwave Health Monitoring Ethical Governance Committee. The main objectives of his unit are to describe the practical, legal and ethical issues faced by populations and small scale biobanks and how these have been addressed; to examine the advantage and disad-



vantages of classical biobanks (disease specific case control studies) versus population biobanks (prospective); to inform scientists and policy makers when making decisions as to whether to develop future retrospective versus prospective biobanks; and to improve governance arrangements by better understanding the problems faced by existing biobanks. In the GeneBanC-project his unit will use qualitative approach. “We will conduct interviews with the scientists responsible for large prospective population biobanks, smaller prospective cohort studies and small disease specific case control registers. We will examine practical, legal and ethical considerations in establishing and maintaining the biobank and/or register. Various questions will be addressed, as for example How are subjects being recruited?; How is informed consent being sought?; How have the future uses of the biobank been defined?; How is confidentiality being maintained?; What measures are in place for data protection?; Who has access to the database?; How have intellectual property rights been addressed? The researcher Marcus Griffin will carry out the interviews and the data analysis.

Legal framework: a comparative approach

Workpackage 4 is divided into two parts, since it will study the legal framework of classical, population and forensic bio-banks in all EU member states as well as on international and European level, which makes it too extensive to be handled by one team. The Budapest team is led by Judit Sándor, professor of law and political science, and director of the Centre for Ethics and Law in Biomedicine (CELAB) at the Central European University in Budapest. She will be carrying out the research together with Petra Bárd. The Leuven team is the team of Herman Nys, professor of Medical Law at the Catholic University Leuven and Director of the Centre for Biomedical Ethics and Law. He will be working on this project with Geraldine Fobelts.

The workpackage aims to study the existing regulatory framework of the establishment, management and functioning of classical, population and forensic bio-banks across the EU. This contains issues like notification, informed consent, privacy, confidentiality, funding, financial gain, supervision, release of tissue samples and withdrawal of consent. The countries the Budapest team will focus on are Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Slovak Republic, Slovenia and Romania. The Leuven team will analyze the laws of Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, Ireland, Luxembourg, Netherlands, Portugal, Spain, Sweden and United Kingdom.



To that extent both teams will collect and analyze legislation and regulations in force in these member states. Legislation and regulations will be collected



through a literature study and a search on the web on one hand and through 2 questionnaires (one for population and classical biobanks, and one for forensic biobanks) that will be sent to two local contact persons per member state on the other hand. Afterwards similarities and differences in the regulatory frameworks will be described. By comparing these similarities and differences, they will be able to look for the “best rules”. In the end, proposals will be made in order to reach, where appropriate, a harmonized regulatory framework across the EU.

This harmonization is crucial, since the law that regulates bio-banks differs in each of the EU member states. For that reason it is very difficult for researchers to cooperate. Nevertheless it is indispensable that they can cooperate in this very important but expensive branch of research, which needs to be carried out on a large scale and is already carried out everywhere in Europe. In addition, on international and European level, as well as in most member states there is no Bio-bank Act. So, even on a national level, there is a large amount of diverse legislation that is all partly relevant. On top of that several topics stay unregulated in certain countries. As a consequence it is very difficult for practitioners to know which rules need to be followed and there are a lot of interests that aren't well protected, like the privacy of



“Proposals will be made in order to reach, where appropriate, a harmonized regulatory framework across the EU.”



Team Leuven		Team Budapest	
Austria	Netherlands	Cyprus	Lithuania
Belgium	Luxembourg	Czech Republic	Malta
Denmark	Portugal	Estonia	Poland
Finland	Spain	Greece	Slovak Republic
France	Sweden	Hungary	Slovenia
Germany	United Kingdom	Italy	Romania
Ireland	Bulgaria	Latvia	

“This workpackage will analyze the inclusion and exclusion criteria of DNA profiles which are currently used for forensic DNA databases”

“The research will help will lead towards a better understanding of the potential parameters of success and failure of contemporary biobank projects.”

Forensic databases

The central focus of workpackage 5 are the ethical and policy issues related to the forensic use of DNA analysis. The introduction of DNA analysis for identification purposes has been considered the most important breakthrough in forensic science since the introduction of fingerprint identification. The efficiency of this type of identification was increased with the establishment of databases containing both samples and profiles. At the same time, however, some concerns have been expressed. Following the lead of the UK, most EU Member States have made it possible to include more and more categories of people in these databases and some proponents have even recommended the creation of population-wide forensic DNA databases. Critics say that these measures could possibly lead to a violation of some important individual rights such as the right to privacy, the right to liberty, the right of moral and physical integrity, the right to health, the dignity of persons and the presumption of innocence. In order to determine what is actually at stake in this debate, this workpackage will start with giving an overview of the existing forensic DNA databases in the EU. Secondly, it will analyze if genetic fingerprinting, ethically

speaking, should be considered different than other forensic techniques (i.e. genetic exceptionalism) and how should individual rights should be balanced against the right of self-defence of a state? Finally, this workpackage will analyze the inclusion and exclusion criteria of DNA profiles which are currently used for forensic DNA databases in the EU and will formulate recommendations concerning these. Kris Dierickx (K.U.Leuven) will be assisted by researcher Nathan Van Camp in carrying out this research.



Governance

The fifth workpackage in the GeneBanC is coordinated by Herbert Gottweis professor at the department of Political Science and head of the Life Science Governance Research Platform (L.S.G) at the University of Vienna. Georg Lauß collaborates with Herbert Gottweis in this workpackage. Based on careful empirical examination of selected biobank projects in a number of countries and on the transnational level, this workpackage will identify specific socio-cultural and economic challenges for the crafting of biobank governance strategy and development. It will analyse how biobank building is a complicated, multi-faceted process that needs to be embedded carefully into highly complex, socio-economic, ethical, scientific-technological, and political-regulatory contexts and depends on the interplay of a number of different, interrelated parameters. The research will help to understand the interplay of these parameters and shall lead towards a better understanding of the potential parameters of success and failure of contemporary biobank projects. An in depth review of the existing social science, natural science, as well as philosophical literature in the field will build a broad information and knowledge base,

on which this workpackage will build up its further research activities. On this basis this unit will conduct field research within five different biobank projects. These case-studies are selected in order to give an insight, both into small scale and population biobanks which deal with different kinds of human specimens. “We adopt a qualitative approach, in which we will conduct a series of semi-structured interviews with major stakeholders of the different cases.” The researcher Georg Lauß will work on that project. The challenge will be to give summary of a highly dispersed and non-uniform array of experience, knowledge and questions concerning “good biobank governance”.





Pascal Borry is postdoctoral researcher and responsible for workpackage 6. The objective of this WP is to enhance internal and external communication. Together with all partners Pascal Borry is responsible for the newsletter, the website, the organization of three workshops, a stakeholder conference, a final conference and an edited book.



Nathan Van Camp studies the ethical and policy issues related to the forensic use of DNA analysis.



Geraldine Fobelets investigates the regulatory framework of biobanks. (K.U. Leuven)



Jan Reinert Karlsen studies the concepts of confidentiality and privacy in the context of biobanks (University of Oslo).



Georg Lauß investigates the governance aspects of biobanks. (University of Austria)



Marcus Griffin (University of Leeds) the practical, legal and ethical issues faced by populations and small scale biobanks



Petra Bárd investigates the regulatory framework of biobanks. (Central European University)



A Scientific Advisory Board has been installed to provide feedback to the research project. Jean-Jacques Cassiman, Anne Cambon-Thomsen, Alastair Kent, Corinna Porteri and David Sheppard are on the picture. Joseph Selling, Dolores Ibaretta and Henk ten Have are also members, but are not on the picture.

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The last few years have witnessed an important expansion of collection and processing of human biological samples and of the related information data. Biobanks are huge repositories of human biological specimens and have a strategic importance for genetic research, clinical care and future treatments. Genebanc is a Specific Targeted Research Project (STREP) funded by the European Commission in the Sixth Framework Programme. This research project aims to investigate the ethical, legal and social issues of three types of biobanks: classical banking, population banking and forensic DNA databases.

www.genebanc.eu

Kick-off meeting GeneBanC in Leuven

On 1-2 December 2006 the Research Project GeneBanC was successfully launched in Leuven with an encouraging support from the EU Project Officer Mary Fitzgerald. GeneBanC is the acronym for the research project *Genetic bio and dataBanking: Confidentiality and protection of data. Towards a European harmonisation and policy*. Genebanc is a Specific Targeted Research Project (STREP) funded by the European Commission in the Sixth Framework Programme and fits in the desired objectives of the Science and Society Work Programme 2005-2006.

The coordinator of the project is professor of medical ethics Kris Dierickx, who works at the Catholic University of Leuven: "Our research project aims to investigate the ethical, legal and social issues of three types of biobanks: classical banking, population banking and forensic DNA databases. Therefore our institute (Centre for Biomedical Ethics and Law) works together with various

institutes who have already gathered expertise in this domain: the Department of Political Science at the University of Vienna (Austria), the Section for Medical Ethics at the University of Oslo (Norway), the Centre for Ethics and Law in Biomedicine at the Central European University (Budapest), the Institute of Health Sciences and Public Health Research at the University of Leeds (United Kingdom). But we hope to make a bridge to many other existing research institutes and research projects working on biobanking."

The next internal meeting of GeneBanc is planned in Paris on 4-5 September 2007. Kris Dierickx: "In 2008 we plan already a stakeholder conference on the topic of the project. In 2009 there will be a conference linked to this project. I suggest everyone to read regularly the project updates on the website and in this newsletter. Only one address: www.genebanc.eu"



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