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Ethical and Legal Requirements for Transnational Genetic Research.

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The ethical and legal challenges of biomedical research are among the most crucial and interesting questions in law nowadays. One of these questions concerns the regulation of research on human genetic data in transnational constellations. Genetic research promises therapies

and prevention for diseases like cancer and HIV, but it is highly dependent on genetic material derived from donors of tissue or blood. For significant advancements in cancer research, for instance, a large number of genetic data of patients is needed. Such data are most effectively collected in and made available by databases or biobanks that allow the exchange of genetic data by various research facilities. To enhance the possibilities and enlarge the amount of genetic data available for researchers the European Union through its 6th Framework Programme of the European Commission under the Action Line 'Integrated biomedical information for better health' funded the so-called 'Advancing Clinico-Genomic Trials on Cancer' research project (ACGT). This project aimed to deliver to the cancer research community an integrated clinico-genomic information and communication technology environment designed to become a pan-European voluntary network connecting individuals and institutions to enable the sharing of data and tools. However, broadening the scope to the European level causes problems of integration of different national views on ethical issues and their legal framework.

The book under review presents some of the findings of the ethical and legal section of the project. The authors, specialists in the field of data protection, data security, and technology assessment, scrutinized the necessary framework for a pan-European infrastructure for medical researchers aiming at a bigger pool of genetic material for research on various types of cancer. Recognizing the necessary link between law and ethics in the realm of biomedical research, the authors combined both of these aspects to provide a holistic socio-scientific analysis of the project, to create a secure and reliable infrastructure for transnational exchange of genetic data for cancer research in Europe, which could further be of use to future projects of transnational genetic research.

The book is accordingly divided into two parts: in the first part it presents the ethical requirements for clinico-genomic trials and in the second part the corresponding legal requirements. The ethics part deals with the issues of informed consent, the right of the donor to know about his or her genetic dispositions, the duty to inform about relevant clinical findings, and the quality of feedback between researchers and donors or patients. The pluralistic nature of transnational research projects is accommodated by avoiding a normative approach to ethics. To find universally acceptable solutions for all partners in such a project the current ethical literature pertinent to clinico-genomic research is evaluated in order to identify current positions and to find out on what issues consensus is reached and where dissent remains. Thus, the principle of informed consent is scrutinized in detail, considering its historical background and its different justifications within different ethical frameworks. Presenting informed consent as a universally accepted ethical principle in medicine and biomedical research is one thing, but – as the authors demonstrate – its application is more difficult, for example concerning the future utilization of genetic material which was originally donated for a narrower purpose. Research that uses genetic data calls for the long-term storage of various materials and analyses, and flexibility for new studies to use previously collected data. However, respect for autonomy and self-determination calls for the provision of information to donors about each specific mode of research on the donors' materials. Broad or blanket consent allowing unlimited future research would thus fail to meet the general standards required by current informed consent doctrine as applied in science. The functionality and practicability of a tiered model of consent, which would give patients the opportunity to choose between various alternatives on different levels and thus legitimize the utilization of their tissue in a more or less restricted manner, is denied by the authors of the book. They thus propose a model that refers to a purpose of intermediate scope (e.g., clinico-genomic research on cancer) in the context of a specific structure (e.g., ACGT), combined with the necessity to ask for renewed consent if the scope of the research changes.

Some other interesting conclusions that the authors draw from their ethical analysis include the requirement of publication of general findings of studies in generally understandable terms and adequate media, like websites and personal mail. Such publication is to fulfil an ethical obligation that the researchers owe to the donors to share information obtained from

the genetic data. Furthermore the authors hold that investigators are similarly obligated to give feedback on relevant specific information to donors accompanied by qualified counseling to make the received information understandable and evaluable for lay people. Further attention is paid to the ethical questions relating to family members who are concerned by the donor's genetic data, i.e., whose personal rights could be affected by the obtaining of information from relatives' data without their own consent, to the ability of minors to consent or assent in research projects, and to the handling of individual predictive cancer prognoses.

The ethics part of the book is, corresponding to the empirical approach, enriched with detailed studies about behaviour, needs and fears of both patients and scientists, and some practical considerations which demonstrate the ability and the will of the authors to provide applicable findings for both their own project and future genetic research projects.

The subsequent legal part focuses on European data protection law laid down in the European Data Protection Directive 95/46/EC. Within this narrow perspective the legal analysis is detailed and elaborated. The accurate scrutiny of the Directive concerned is followed by its adequate application to the specific issues of genetic research in Europe. The authors focus on the anonymization of genetic data, which would enable researchers to process such data without the restrictions national laws impose in line with the Directive, since anonymized data do not give rise to the same fundamental rights protection as personal data. The question is, however, whether it is possible to anonymize genetic data. Two problems are raised here: on the one hand it is necessary to keep an identifiable link between the donor and his genetic data to be able to give feedback on relevant findings connected to donor's genetic data, a requirement which was declared ethically mandatory. Hence only pseudonymization is an option for genetic research. On the other hand, the uniqueness of genetic data must be taken into consideration. Every reference datum makes it possible for third persons to match data and identify the donor. Thus, it is not possible to render genetic data completely anonymous, but rather *de facto* anonymous, given that reference data are available. The interests of life insurance companies or law enforcement authorities in particular in genetic data threaten the fundamental rights of donors.

In the realm of transnational genetic research projects the authors propose a framework of technical and legal measures entitled the 'Data Protection Safety Net' to ensure the ability to process pseudonymized or *de facto* anonymized genetic data within a European network. It is based on three pillars which are to guarantee both the protection of the donors' rights and the progress of scientific research. The first pillar comprises a process of pseudonymization with as intermediary a trusted third party, who acts as a security authority keeping the link between the pseudonym and the corresponding real name of the patient. Such a procedure is meant to ensure the separation of data processors and potential identifiers within a closed network of research units. The major fallback scenario for a failure of that system is to be the second pillar, which calls for the qualified informed consent of each patient to the processing of his/her data within the system. The respective consent modes are derived from the ethical part of the book and specified for each problematic case to make them legally applicable in a contractual fashion. The third pillar, for the 'very unlikely' case that both the other two pillars should fail adequately to protect the donor, builds on the various exemptions in the national laws of the Member States of the European Union, allowed for by Article 8 of Directive 95/46/EC.

The whole model includes further provisions to guarantee the full exercise of the donors' rights deriving from data protection law, such as their right of access to personal data and litigation in case of infringements. The authors propose that a central data protection authority should be established to grant additional contractual rights to the data subjects (i.e., the donors or patients), which would allow them to sue not only the central authority but the data receiving end users as well.

The book under review is remarkable in that it presents a complete technical and legal framework to enable researchers to build a European research infrastructure that promises

further scientific advancement in the therapy or prevention of diseases. The question remains whether the aim of the book to provide solutions for future international genetic research infrastructures can be achieved. The starting point of the book is the European legislation on data protection that is quite specific, reflecting the original research project's aim to create such an infrastructure for the European region. It could be argued that had the authors really sought a universally applicable solution, they should have put more emphasis on the framework of international and national fundamental rights, their scope, and interpretation. While the ethical considerations of this book represent a global approach, the legal ones are geared to European Union law, which may be the most elaborated data protection law, but not the only one. To broaden the scope it might have been helpful to take into consideration other international frameworks as well, e.g., the ECHR, the International Covenant on Civil and Political Rights, and the OECD and UN Guidelines concerning data protection. In any case the findings presented can be used at least to create new European infrastructures in genetic research for further projects, which is a notable advancement.

Another point that might benefit from clarification is the link between law and ethics. It would have been helpful to clarify the exact nature of the so-called ethical guidelines like the UNESCO declarations on human genome and bioethics, as well as the Convention of the Council of Europe on Human Rights and Biomedicine which is consulted as the 'ethical foundation' of the right to individual feedback on research results. The link shines through in some chapters, for example when the authors conclude that a legal obligation to acquire consent from a minor or intellectually disabled person does not exist, but that it would be highly recommendable to obtain consent 'from an ethical point of view'. A complete theoretical clarification of this issue would, however, have exceeded the scope of this book, as the authors tried to generate applicable and understandable guidelines for genetic data generation and protection for the European region.

Readers will enjoy a detailed analysis of informed consent from an ethical and legal perspective, and furthermore an excellent compendium of legal analysis concerning genetic data protection in Europe. Policy-makers, professionals, and researchers who search for a complete and elaborated ethical and legal framework for genetic research in (European) transnational constellations will certainly benefit from this volume.

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