

QUEEN'S UNIVERSITY BELFAST

European Master's Degree in Human Rights and Democratisation

A.Y. 2013/2014

TO RESPECT OR TO HEAL?

EU Data Protection Reform to Threaten Medical Research.

Finding a Balance Between Two Human Rights.

Author: Norbert Ostró

Supervisor: Dr. Mark L. Flear, LL.M., PhD.

Abstract

In this thesis I will deal with the latest changes in EU Data Protection Regulation regarding health data processing in medical research. I will argue that some of the EU Parliament Committee's proposed amendments impose serious restrictions that may unintentionally threaten scientific advancements in a number of areas. I will try to explain how the implementation of those amendments would make much research involving personal data at worst illegal, and at best in some cases even unworkable. The way to do this is going to be done by comparison and analyses. I will try to answer which kinds of research might be threatened and where and how to find a balance between the two human rights.

Keywords:

health data, European Union, European Parliament, ECtHR, Directive 95/46/EC, Data Protection Regulation

Table of content

| | |
|---|----|
| Introduction | 7 |
| 1. Medical research..... | 10 |
| 1.1. European rules for medical data research..... | 11 |
| 1.2. Privacy and confidentiality of medical data | 14 |
| 1.3. Meaning and the use of anonymised and pseudonymised data | 15 |
| 1.4. Impact of the draft proposal on clinical trials..... | 18 |
| 1.5. Which research would be harmed?..... | 19 |
| 1.6. Legal problems in research practice | 21 |
| 1.7. Right to privacy vs. freedom of research..... | 23 |
| 2. EU Health Data Protection | 24 |
| 2.1. Current state of EU Health Data Protection - Directive 95/46/EC..... | 24 |
| 2.2. Free movement of personal data with respect for the right of privacy as the aim of the current Directive..... | 25 |
| 2.3. Article 8 - the processing of medical data | 27 |
| 2.3.1. Prohibition of medical data processing | 28 |
| 2.4. Comparison of the data harmonization in the European countries..... | 30 |
| 2.5. What does the current Directive provide regarding medical data communication between researchers? | 31 |
| 2.6. Why do we need a revision of the Data Protection Directive?..... | 33 |
| 3. New EU Data Regulation | 35 |
| 3.1. Genesis of the legislative process..... | 35 |
| 3.2 Introduction to changes | 37 |
| 3.3. EU Commission's Proposal..... | 39 |
| 3.4. LIBE - European Parliament Committee on Civil Liberties, Justice and Home Affairs Proposal..... | 40 |

| | |
|--|----|
| 3.5. Deeper comparison of some selected articles | 41 |
| 3.5.1. Definition of personal data | 41 |
| 3.5.2. Pseudonymised data in medical research | 42 |
| 3.5.3. Data concerning health | 47 |
| 3.5.4. Informed consent – processing of personal data concerning health..... | 48 |
| 3.6. Case Study: requirement for explicit consent..... | 53 |
| 3.7. Threaten or facilitation of medical research? | 54 |
| | |
| 4. Case law of the ECtHR in Strasbourg | 58 |
| 4.1. Introduction | 58 |
| 4.2. Private Life | 58 |
| 4.3. Data Protection | 59 |
| 4.4 Health Data Cases..... | 60 |
| 4.4.1. Protection against Public Actors..... | 60 |
| 4.4.2. Protection against Private Actors..... | 68 |
| | |
| 5. Conclusion..... | 70 |
| | |
| 6. Bibliography..... | 72 |