DATA PROTECTION AND MEDICAL RESEARCH IN EUROPE: PRIVIREAL

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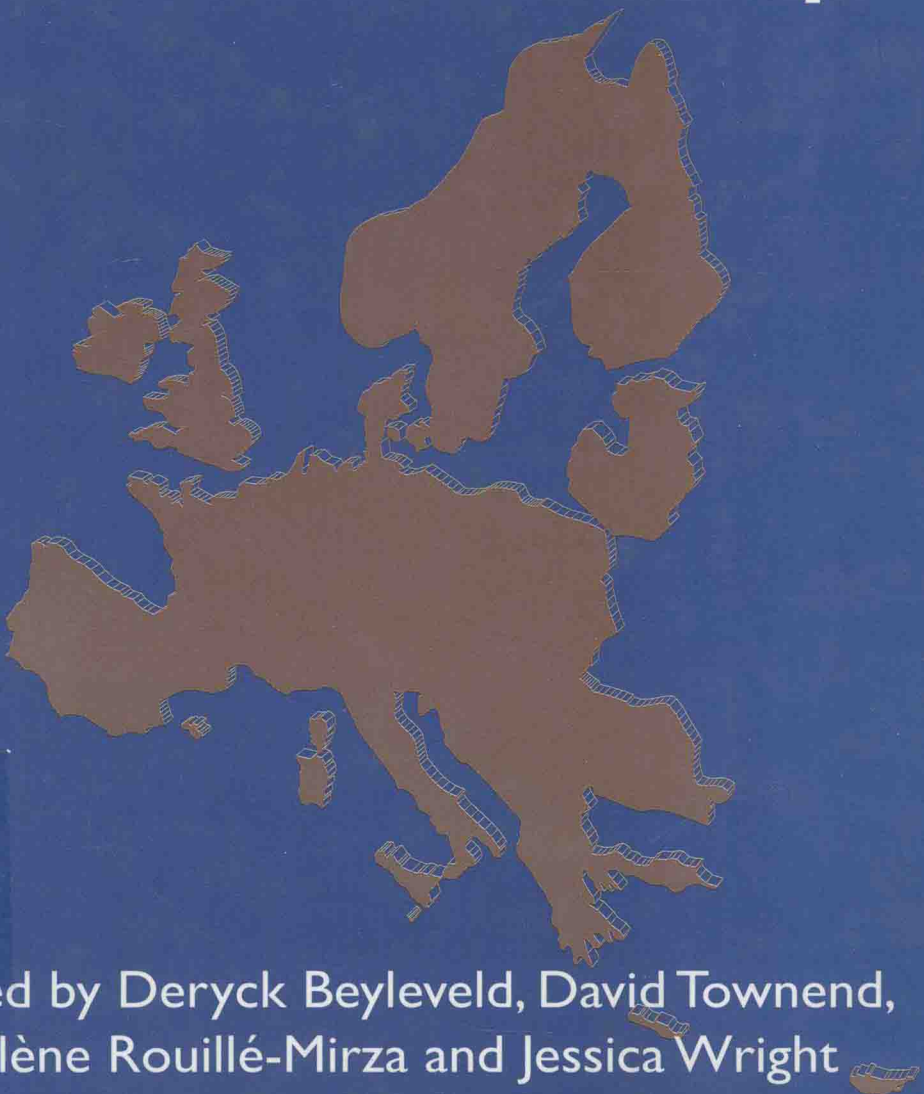
The Data Protection Directive and Medical Research Across Europe



Edited by Deryck Beyleveld, David Townend, Ségolène Rouillé-Mirza and Jessica Wright

The Data Protection Directive and Medical Research Across Europe

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THE DATA PROTECTION DIRECTIVE AND MEDICAL RESEARCH ACROSS EUROPE

Data Protection and Medical Research in Europe: PRIVIREAL

Series Editors:
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PRIVIREAL, Sheffield Institute of Biotechnological Law and Ethics

PRIVIREAL (Data Protection and Medical Research in Europe) is a European Commission funded project examining the implementation of Directive 95/46/EC on data protection in relation to medical research and the role of ethics committees in European countries. PRIVIREAL members and authors are experts in their fields from each country, and the project is co-ordinated by Professor Deryck Beyleveld, Faculty of Law, University of Sheffield.

The PRIVIREAL series consists of five separate volumes following the development of the PRIVIREAL project, from first assessments of the implementation of the Directive and its impact on medical research, to consideration of the role of research ethics committees and data protection in practice, leading to recommendations and suggestions to the EC on the implementation of the Directive and the remit to be given to RECs to protect research participants' rights.

The information collected in this series provides a valuable resource for those involved with data protection, medical research, and how they interact. The volumes work to present a comprehensive view of current proceedings right across Europe, including both New Member States and Newly Associated Member States.

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Foreword

Today, fundamental advances in medical science have extended the possibilities for and expectations of medical practice to extraordinary levels. Within this field, as in all other areas of commerce, culture and society, technology offers limitless possibilities of data processing adding to the potential for developing new medical research, diagnostic procedures, treatments and benefits for all. At such times the vulnerabilities of individuals can be most at risk. The development of a coherent and effective ethical and legal framework within which the individual can receive appropriate protection must be made alongside the advances. Such ethical and legal developments must be independent and carefully reasoned to justify any slowing of the undoubted benefits that science and technology bring to the many, but they are essential to safeguard the individual.

PRIVIREAL has the opportunity to make such an independent investigation through the opportunities provided by the Fifth Framework programme of the European Commission's research programme, and especially through the initiative and vision of the Science and Society directorate within the Commission. We are particularly grateful to Drs. Rhoda, Salvi, Sachez, and Pitkanen in the Science and Society Directorate for their enthusiasm and encouragement in developing PRIVIREAL, and especially to Drs. Sachez and Pitkanen for their work as project managers within the Commission.

The coordination of PRIVIREAL has been undertaken in the University of Sheffield in the Sheffield Institute of Biotechnological Law and Ethics (SIBLE), and particularly in the School of Law. Without the confidence and commitment to the project shown by Professor John Birds, Head of the School of Law, we would not have been able to undertake the project, and certainly not to integrate the Newly Associated States into the programme at its earliest stages. We are extremely grateful to him.

Throughout PRIVIREAL, and especially before permanent staff could be appointed, a small number of people within the School of Law have worked with us on the project. Their work enabled us to establish the framework of the project and then to maintain it on a strong footing. We are very grateful to them: they are Marie-Jo Goode, Anna Greene, Joy Pierson, Sebastian Sethe, Susan Wallace, David Moxon, Jane Miller, and Rebecca Wong. We are also blessed to have in SIBLE a number of very strong and capable students reading for the MA in Biotechnological Law and Ethics. They often join in SIBLE projects, and some—Daniel Byrne, Adrienne Hunt, Chantal D. M. Gill'ard, Maria del Mar Gonzalez, Christian Lopez Silva, and Fang Wang—worked for PRIVIREAL on the preparation of comparative tables and in compiling information for reports to assist us.

Concerted Action projects bring together those who are experts into one place for short times to share ideas and information. Quiet efficiency in the arrangements

and a warm welcome ensure that the meetings can be their most fruitful, and we were served very well in Sheffield. The first PRIVIREAL workshop was held at Stephenson Hall in the University of Sheffield. We thank Alan Walker and his staff, and also Brenda Styran and the staff of the Cutlers' Hall where we enjoyed the Conference Dinner, for their hospitality. Mrs Carol Heathcote, the PRIVIREAL secretary, produced excellent work dealing with the enormous task of arranging the travel for all the delegates (from each of the EU member countries, Norway, and from the Newly Associated States), caring for them while they were in Sheffield, and, perhaps most importantly, maintaining friendly and enthusiastic links with them throughout the project. We owe her the greatest debt of thanks.

We are very grateful to those who have helped in the production of this book. In Sheffield, we are grateful to both Rosemary Gumbley and Matthew Wisbey, the PRIVIREAL (NAS) secretaries, who joined the project after the first workshop and have assisted with the production of the copy for publication. We are also enormously grateful to John Irwin, Alison Kirk, Pam Bertram, and their colleagues at Ashgate for their patience and encouragement in developing the books in this series.

Concerted Actions would be nothing without the network of participants, members of the project who give their time to share their research, discuss new perspectives, and forge new understandings. The PRIVIREAL network is remarkable not only because of its coverage—having representation from all the Member States—but also because of the quality and enthusiasm of the members. It is a great pleasure and privilege working with the network, many members of which are contributors to this book, and are central to the success of PRIVIREAL. We are enormously grateful to them all.

Deryck Beyleveld
David Townend
Ségolène Rouillé-Mirza
Jessica Wright

Sheffield, 2004

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PART I
INTRODUCTION AND KEYNOTE PAPERS

Chapter 1

Introduction

Deryck Beyleveld, Ségolène Rouillé-Mirza, David Townend
and Jessica Wright

The papers in this volume contain keynote papers given at the first workshop of the EC funded 5th Framework Programme concerted action project, 'Privacy in Medical Research and Law' (PRIVIREAL) (PL QLRT-2001-00056), which took place at the University of Sheffield from 9–12 January 2003. The volume also contains an overview of Directive 95/46/EC on Data Protection, with special emphasis on provisions with implications for medical research, and a report on the implementation of this Directive in the EU Member States and the Newly Associated States (NAS), the majority of which are now EU members, again with special emphasis on medical research. This report was compiled from papers prepared by experts in the countries concerned who are partners in the PRIVIREAL project (with the exception of Cyprus and the Slovak Republic, on which information was not received). These papers are published in a separate volume. It is appropriate for this project to maintain the distinction between pre-2004 Member States and the group formerly known as the NAS because the duties in relation to the implementation of the Directive are different between the two groups. The term 'NAS' is therefore used to indicate Bulgaria, the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic, and Slovenia; 'EU Member States' refers to pre-2004 Member States.

Aims of PRIVIREAL

Protection of privacy of subjects in medical research depends as much on ethics review as on data protection law, but little is known about how this interacts with implementation of Directive 95/46/EC to protect privacy. PRIVIREAL brings together experts on relevant law and on ethics review of medical research from across all the EU Member States (except Luxembourg, which is nevertheless covered) and Norway (like Iceland and Liechtenstein, a member of the European Economic Area but not the EU, but which has agreed to be bound by Directive 95/46/EC) as well as the NAS, to evaluate the interaction between implementation of the Directive and research ethics review in protecting Directive rights of research subjects, with a view to making recommendations to the Commission about how to optimize the protection provided by research ethics review (taking

into account the background EU and domestic legal and ethical culture/s).

To carry out these aims, PRIVIREAL has three phases. In the first phase, leading to the first PRIVIREAL workshop, what the partner countries have done, or plan to do, to implement Directive 95/46/EC in relation to medical research is ascertained, and the adequacy of this is evaluated in relation to the requirements of the Directive. This volume and its companion present the results of this phase. In the second phase, which led to the second PRIVIREAL workshop (Helsinki from 14–17 August 2003), the remit and practice of ethics committees reviewing medical research (RECs) in relation to legal requirements generally and those of data protection law, in particular, were ascertained. In the third phase, which is the concern of the final PRIVIREAL workshop (Coimbra in July 2004), the protection of privacy of medical research subjects resulting from domestic implementation of Directive 95/46/EC together with the remit and practice of RECs to protect data protection rights of medical research subjects will be evaluated in the context of domestic legal and ethical culture in relation to the objectives of Directive 95/46/EC, and recommendations will be made to the European Commission about what it might do to better protect privacy of medical research subjects where protection is judged to be inadequate. The results of the second and third phases will also be published by Ashgate Publishing Ltd.

Methodology of PRIVIREAL

The primary source of data is reports by experts in the partner countries. However, central to the project is a website (http://www.privireal.org). This contains relevant legislation and guidance on the topics of relevance to the project, with as much as possible being made available in translation to English as well as the original language. To assist with the second and third phases of the project, there is a questionnaire for RECs that can be completed on-line in English, French or German. There is also a public discussion forum in addition to sections that can only be accessed by the partners. The website is complementary to the published volumes, and readers of the volumes are invited to consult the website and use it actively.

The workshops have been only open to partners of PRIVIREAL. The purpose of the first two workshops was primarily to enable partners to discuss summaries and analyses of the material they submitted which form the basis of the reports prepared for the first two phases by the co-ordinating team. The purpose of the third workshop is to discuss and prepare recommendations for the European Commission. The first two workshops also provide for keynote papers given by invited partners or by persons from outside to discuss controversial, but crucially important, topics for the relevant phase of the project. These papers do not represent a consensus among the partnership. They are merely the views of their authors. Only in the recommendations will concerted statements and judgments (where possible) be made.

Chapter 2

An Overview of Directive 95/46/EC in Relation to Medical Research

Deryck Beyleveld[1]

Introduction

This chapter outlines the provisions of Directive 95/46/EC with the use of personal data for medical research centrally in mind. The Directive makes no specific mention of medical research and, consequently, it contains no provisions for medical research as an explicitly delineated category. However, at times, the Directive refers to medical purposes (though medical research is not explicitly listed under this category) and there are provisions relating to the use of data relating to a person's health. It also refers to the use of personal data for scientific research or statistics. Consequently, this overview is an analytic construction from these related provisions together with any other of the Directive's provisions that could apply to medical research, including those of a wholly general nature that apply to any processing of personal data.

The overview that follows represents my personal view, rather than the collective view of the participants in the PRIVIREAL project. It is presented here for the benefit of the general reader and also because it might assist in understanding the questions that participants were asked to address for the purpose of gathering the information for the comparative analysis presented in Chapters 10 and 11.

Objective of the Directive

The purpose of Directive 95/46/EC is to enable the free flow of personal data from one European Union (EU) Member State to another for the purposes of the internal market by ensuring that fundamental rights and freedoms of individuals (in particular, privacy) are safeguarded (see Recitals 3 and 10 and Article 1(1)) and a high level of equivalent protection of these rights and freedoms is ensured in all the Member States (see Recitals 7 and 8). The Directive gives substance to and amplifies the fundamental rights and freedoms contained in the Council of Europe

[1] Privireal Co-ordinator.

Convention of 28 January 1981 for the Protection of Individuals with regard to Automatic Processing of Personal Data (see Recital 11). Since at least the *Second Nold Case (Case-4/73)* [1974] E.C.R. 507, the European Court of Justice (ECJ) has recognized, at least in principle, that violation of fundamental rights as fundamental principles of EC law (in which are included the fundamental rights and freedoms of the European Convention on Human Rights (ECHR) of the Council of Europe [which is alluded to in Recital 10]), is sufficient to invalidate at least *secondary* Community Acts.[2] However, despite the fact that a commitment to fundamental rights and freedoms has subsequently been enshrined in Article 6 of the Treaty of European Union (the 'Treaty of Maastricht'), it must not be forgotten that the EU does not have competence to legislate for fundamental rights and freedoms *for their own sakes.* The legal basis of EC law generally lies in the aim of constructing a single European market (and the legal basis of the Directive lies specifically in the aspect of the single market referred to as 'the internal market'). Thus, the competence of the EU to legislate to protect fundamental freedoms and rights only arises for the reason that this protection is deemed necessary for achieving the purposes of the single market. For this reason (as well as for the reason that the Directive is concerned in its attention to fundamental rights and freedoms not only to protect privacy but all fundamental rights and freedoms to the extent that they may be interfered with in the use of personal data)[3] it can be misleading to refer, as is often done, to the Directive as 'the Privacy Directive'.

Article 1(2) asserts that Member States shall not restrict or prohibit the free flow of personal data between themselves for reasons connected with the protection of fundamental rights and freedoms. However, this does not mean that the Directive is essentially concerned with legislating a balance between fundamental rights and freedoms and economic objectives of the internal market (let alone that the purpose of free flow between Member States overrides all considerations of fundamental rights and freedoms). Instead, adequate safeguarding of fundamental rights and freedoms must be viewed as a condition of the free flow of personal data, in line with which Article 1(2) signifies, primarily, that if a Member State (A) implements the Directive correctly then another Member State (B) may not restrict or prohibit the flow of personal data from B to A because B does not consider the level of protection for fundamental rights and freedoms provided by A's implementation to be adequate (see Recital 9). Presumably, it also means that if B does not consider that A provides the protection required by the Directive, then B may not restrict or prohibit the flow of personal

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[2] Manfred A. Dauses, 'The Protection of Fundamental Rights in the Community Legal Order' (1985) 10 *European Law Review* 398–419, at 407, argues (on the basis of Articles 53 and 64 of the Vienna Convention on the Law of Treaties 1969, according to which any treaty is void if it violates a peremptory norm of general international law) that, in theory, violation of at least some fundamental rights is sufficient to invalidate even the European Treaty itself. However, it must be remembered that the ECJ has no jurisdiction to rule on the validity of the Treaty (see Article 234 EC (ex Article 177)).

[3] This is because the words 'in particular privacy' in Article 1(1) mean 'especially privacy' not 'only privacy'.

data from B to A on that ground either (but should refer the matter to the Commission or the ECJ). This, however, is not to say that the Directive is not concerned with a balance between economic objectives and the protection of fundamental rights and freedoms. However, such a balance is best viewed, in my opinion, as 'internal' to the activity of protecting fundamental rights and freedoms rather than as signifying a conflict between the protection of fundamental rights and freedoms as such and other factors. This is because to view the matter 'internally' is to observe that, e.g., Article 8(1) (the right to private and family life) of the ECHR may be derogated from in terms laid down by Article 8(2) ECHR, and relevant considerations include the economic well-being of the country, and may include economic objectives more generally to the extent that they serve, e.g., the fundamental rights and freedoms of others, or the public interest. To view the matter 'externally', on the other hand, requires the objectives of the internal market to be seen as in conflict with the entire framework set up by, e.g., Article 8(1) *together with* Article 8(2), which is both unnecessary and not consistent with the concept of a *fundamental* right or freedom.

Definition of Personal Data and Scope of the Directive

The Directive defines personal data as any information relating to an identified or identifiable natural person ('data subject') (see Article 2(a); Recital 26), and this includes 'sound and image data relating to natural persons' (see Recital 14). An identifiable person is, in turn, defined as a person who can be identified directly or indirectly from the data in conjunction with other factors (see Article 2(a)) 'likely reasonably to be used' by any person (see Recital 26—which also specifies that codes of conduct under Article 27 may provide guidance about when data have been rendered anonymous).

Recital 26 states that the principles of data protection (see below) apply to all personal data (within the scope of the Directive), but that they do not apply to data that have been rendered anonymous so as to render the data subject no longer identifiable (i.e. that has rendered the data non-personal). That data remains personal if *any person* is reasonably likely to be able to identify the data, seems to imply that data are not to be considered anonymous for the purposes of processing by a data controller (whom Article 2(d) defines as any person or body (private or public) that individually or jointly determines the purposes and means of processing) who cannot identify the data subject directly or indirectly from the data if any other person is reasonably likely to be able to identify the data subject directly or indirectly. If so, the circumstances in which data may be considered anonymous are extremely limited. However, precisely when data may be considered to be rendered anonymous and whether (and to what extent) processing of data in anonymous form that has been collected in personal form falls under the