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Sigmund Simonsen

Acceptable Risk in Biomedical Research

European Perspectives

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Preface

The topic of this book is the legal requirement of proportionality between risks, burdens, and potential benefits in interventional biomedical research on human beings. The book is based on my more extensive doctoral thesis, which was delivered June 2009 and defended February 2010.

The topic was chosen after an investigation of biomedical research law, which revealed that surprisingly little appeared to be known about this old and obviously central professional, ethical, and legal requirement. Although more information about the requirement was found later on, the requirement of proportionality in European biomedical research law appeared largely unexplored in legal theory, in European Convention (ECHR) law and Community (EU) law.

The purpose of this book is to contribute to enhanced knowledge about the requirement's normative content in the first two jurisdictions, and, consequently, also in national law of European countries. Hopefully, this clarification of the law may improve assessments of proportionality in practice, and consequently improve the respect for and protection of research participants' individual interests, welfare (including health), and human dignity.

I am enormously grateful and indebted to many persons who have generously contributed during the course of this project. Firstly, I am grateful to my enthusiastic mentor and principal supervisor of the doctoral project, Professor Dr. med Magne Nylenna. I am also very grateful to my co-supervisors: Judge Sverre Erik Jebens, Professor Dr. Philos Knut Ruyter, Judge Øyvind Smukkestad, and last, but not least, Professor Dr. Juris Henriette Sinding Aasen.

I must also thank the opponents of the doctoral committee for a constructive critique; Professors Mette Hartlev, Asbjørn Kjønstad, and Steinar Westin.

This project was jointly funded by the Norwegian University of Science and Technology (NTNU) and Middle Norway Regional Health Authority. Many thanks to former dean, now director, Gunnar Bovim, for recruiting me. My place of work has been and still is the Department of Public Health and General Practice, at the Faculty of Medicine, NTNU. Working in a biomedical research community has been enriching, and I am grateful to my many good and caring colleagues there. I also wish to thank service minded librarians at the Medical Library at NTNU, the Kennedy Institute of Ethics at Georgetown University, and the European Court of

Human Rights. Many thanks also to Head of Bioethics Division, Laurence Lwoff, of the Council of Europe for meeting and valuable assistance.

Special thanks goes to the members and the secretaries of the Research Ethics Committee (REC) in Middle Norway, who open-heartedly let me observe their conscientious work for three years to learn about the assessment of proportionality in practice.

Sincere gratitude to three seniors: The Danish Professor Dr. med Povl Riis, who participated in the drafting of both the Declaration of Helsinki and the Additional Protocol, and who kindly invited me to his home for a long initial talk on the topic; Professor Dr. med Hermod Petersen, for discussions on the history of biomedical research; former editor of the British Medical Journal (BMJ), Dr. Stephen Lock, who has patiently read the manuscript twice (!) to improve the English language. Yet, remaining mistakes are all mine. I would also thank anonymous referees, Maja de Keijzer and Nicoline Ris at Springer for all the help.

Warm thanks to my beloved and supportive wife, Kirsti, and our adorable and lively boys, Simon, William, and Filip – my shining stars.

Finally, I express profound gratitude to my dear parents, to whom I dedicate this work.

Trondheim, Norway
25 August 2011

Sigmund Simonsen

Abbreviations

Regulatory Instruments

Additional Protocol	CoE Additional Protocol on Biomedical Research to the Oviedo Convention of 2006
Clinical Trials Directive	Directive 2001/20/EC of the European Community
Declaration of Helsinki	Professional guidelines first adopted by the World Medical Association in 1964, last revised in 2008
GCP Directive	EU Commission Directive 2005/28/EC
ICCPR	UN International Covenant on Civil and Political Rights of 1966
ICESCR	UN International Covenant of Economic, Social, and Cultural Rights of 1966
Oviedo Convention	CoE Convention on Human Rights and Biomedicine of 1997
UDHR	Universal Declaration of Human Rights of 1948
UN Charter	Charter of the United Nations of 1945

Other Abbreviations

CIMOS	Council for International Organizations of Medical Sciences
CoE	Council of Europe
EC	European Community
ECHR	European Convention on Human Rights of 1950
ECJ	European Court of Justice
ECtHR	European Court of Human Rights
EEA	European Economic Agreement [EØS]
EU	European Union
Explanatory report	The Explanatory report to the Additional Protocol
GCP	Good Clinical Practice (standards for professional clinical trials with pharmaceutical products (drugs))
ICH	The International Conference on Harmonisation (Adopted guidelines for Good Clinical Practice (GCP) in 1996)

ICJ	International Court of Justice
IRB	International Review Board (found in the US, equals REC)
REC	Research Ethics Committee (multidisciplinary agency)
UN	United Nations
UNESCO	UN Economic, Social, and Cultural Organisation
WHO	World Health Organisation (UN)
WMA	World Medical Association (professional organisation for physicians)

Contents

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List of Figure and Tables

Part I
Initial Issues

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