

# Legal and Ethical Aspects of HIV-Related Research

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To Robert D. Debner, Jr.

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# Preface

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The motivation and inspiration for this book come directly from experiences with clients during the years that I practiced HIV-related law at the Legal Aid Society of San Diego, Inc. The issues discussed in this work reflect issues that arose on a recurring basis with clients participating in HIV research studies, with investigators calling for guidance on the legal implications of particular aspects of their proposed studies, and with research institutions and health care facilities struggling to make sense of legal maneuvers aimed at obtaining the records of their HIV-infected patients. It is impossible to thank each of these persons individually for their provocative questions and their insights.

The discussion of ethical and legal issues relating to the design of clinical trials reflects questions raised during discussions with Donald J. Slymen, Ph.D. Don was one of the first researchers, in my realm of experience, to pay close attention to ethical concerns, and I am greatly appreciative of his contribution to both my professional growth and the development of various scenarios discussed in this text.

The portions of this text dealing with confidentiality are the result of many hours of thoughtful discussion and analysis with Penn Lerblance, J.D., now deceased and still missed. Penn and I often participated together as presenters of in-service training programs for health professionals. Penn addressed discrimination, and I focused on confidentiality. Our long and detailed debates on legal issues yet unresolved by the courts and the legislatures helped to focus the discussion here.

Many of the examples pertaining to scientific misconduct in the context of HIV research were obtained from Peter Lurie, M.D., M.P.H. I greatly appreciate his generosity in sharing these materials with me.

I am appreciative of colleagues' comments on earlier drafts of the manuscript and of their guidance in striking a balance herein between

theory and practice. Several individuals reviewed earlier drafts of the manuscript critically and provided me with extensive constructive criticism. I thank, in particular, Linda S. Lloyd, Dr.P.H., Dean Chaisson, M.D., and Lynn Sivinski, J.D., M.P.H. This book would not have been possible without the able research assistance of Jacqueline Love-Baker, J.D., and her constructive and detailed critique of earlier versions of this work.

I am also grateful to my editor at Plenum Publishing, Mariclaire Cloutier, for her support and her wonderful sense of humor throughout the writing process. Everyone should be blessed with such an editor.

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# Introduction

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As of March 31, 1993, the Centers for Disease Control and Prevention (CDC) had reported a cumulative total of 289,320 AIDS cases and 182,275 AIDS-related deaths in the United States. CDC has estimated that there are over one million HIV-infected individuals in the United States, with approximately 40,000 new infections each year (California Department of Health Services, 1993).

Figures worldwide are equally alarming. As of the end of 1991, a cumulative total of 446,636 cases of AIDS had been reported globally. The World Health Organization estimates, however, that there were 1,475,000 cumulative adult AIDS cases by the end of 1991 (Tarantola, Mann, Mantel, & Cameron, 1994). Increase in the numbers of persons infected and affected by HIV has been particularly notable in several African countries, including Zaire and Uganda, and in parts of Southeast Asia, including Thailand.

Clearly, these increasing numbers and the human and economic costs of HIV infection provide the impetus for HIV research. Currently ongoing research efforts span a large number of disciplines, encompassing both the biological and the behavioral sciences. As AIDS research efforts increase in both number and intensity, it becomes even more crucial that researchers be cognizant of the legal and ethical implications of their actions, in order to protect themselves, the research participants, and the sponsoring research institutions from harm.

This book represents an effort to advise HIV researchers and individuals interested in pursuing HIV research of the basic legal and ethical principles related to such research. The text may also be useful to attorneys, who find that they are called upon to advise researchers and research institutions of the legal implications of their actions, but

who may have little or no familiarity with the scientific principles involved. The book attempts to strike a balance between theory and practice. All too often, researchers may be provided with the underlying ethical and legal concepts applicable to their situations, but with little guidance on how to actually implement those principles in a specific context.

The organization of this book follows the sequence of a study: prestudy planning, issues that may arise during the course of the study, and issues that generally arise after the conclusion of the study. The fourth portion of the text addresses roles not traditionally encompassed within the scope of scientific research, such as legislative advocacy and appearances as an expert witness. These situations may arise both during and after the course of a study.

Part One, Prestudy Planning, reviews the evolution of protections for research participants and the ethical principles governing the conduct of scientific research. Special attention is paid to the conduct of clinical trials. Part Two focuses on issues relating to confidentiality and mandatory reporting of HIV status or AIDS, potential conflicts that may arise during the course of the study, and scientific misconduct. Part Three addresses responsibilities vis-a-vis the study participants and the scientific community. Part Four provides an overview of the judicial, legislative, and administrative systems on both a federal and state level, and suggests ways in which the HIV researcher can utilize his or her expertise in these arenas. Each chapter may be read singly or in conjunction with other related sections. Cross-references to related portions are provided throughout the text.