## Table of Contents

Letter of Transmittal to the President		Chapter 5: Ensuring Voluntary Informed Consent and Protecting Privacy and Confidentiality	97
National Bioethics Advisory Commission		Introduction	97
National Bioethics Advisory Commission Staff and Consultants		Voluntary Informed Consent	97
Prologue	i	Privacy and Confidentiality	104
Summary of Recommendations	xi	Summary	107
Chapter 1: Introduction—The Need for Change	1	Notes	108
Introduction	1	References	108
The Value of Research	1		
The Need for Oversight of Research Involving Human Participan		Chapter 6: Conduct of Research—Selected Issues for Local Institutions	r 111
Current Factors Influencing the Research Enterprise	4	Introduction	111
Major Challenges Facing the Current Oversight System	8	Monitoring of Ongoing Research	111
Consequences of a Flawed System	16	Review of Cooperative Research Studies	117
Notes	16	Compensation for Research-Related Injuries	123
References	18	Summary	126
References	10	Notes	127
Chapter 2: A Proposal for Oversight	21	References	128
Introduction	21		
Purpose of Oversight	21	Chapter 7: Implications of This Report	131
Functions and Responsibilities of the Oversight System	23	Introduction	131
Scope and Structure of a Revised Oversight System	26	Resources	131
The Need for a Unified, Comprehensive Federal Policy	28	Future Research	133
Definition of Research Involving Human Participants	32	The New System as a Dynamic and Responsive Structure	134
Summary	42	General Themes in the Recommendations	135
Notes	42	What This Report Means to Those Who Use the System	136
		How This Report Will Affect Institutional Review Boards, Investigators, and Institutions	136
References	43	How This Report Will Affect Research Participants	137
Chapter 3: Methods for Ensuring Protection:		Summary	137
Education, Certification, and Accreditation	45	Notes	137
Introduction	45	References	138
Education and Competence in Conducting Research Involving			
Human Participants	45	Appendices	
Mechanisms to Ensure Institutional, Institutional Review Board,	~ 2	A. Acknowledgments	139
and Investigator Compliance	50	B. May 1999 Letter from Harold T. Shapiro to President William J. Clinton and President Clinton's	
Conflicts of Interest	58	Response	141
Summary	64	C. The Current Oversight System: History and Description	151
Notes	64	D. The Belmont Report	161
References	65	E. Code of Federal Regulations, Title 45 Part 46	169
Chapter 4: Assessing Risks and Potential Benefits and		F. Code of Federal Regulations, Title 21 Parts 50 and 56	187
Evaluating Vulnerability	69	G. Statutory Authority for Agency Human Subjects Protection Regulations (Common Rule)	205
Introduction	69	H.Food and Drug Administration Regulations Requiring	
Institutional Review Board Approval of Research	69	Reporting of Adverse Events	213
Risks of Harms and Potential Benefits to Participants and to Society	71	I. Public Comments on NBAC's December 19, 2000, Draft	217
Vulnerability	85	J. Public and Expert Testimony	221
Summary	93	K. Commissioned Papers and Staff Analysis	225
Notes	93		
References	95	Index	227