

In preparation for writing the Belmont Report the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research invited a number of experts to submit papers.

Volume I (DHEW Publication No. (OS) 78-0013

Volume II (DHEW Publication No. (OS) 78-0014)

I. Preliminary papers prepared for the Commission by Robert J. Levine, M.D.

1. The boundaries between biomedical or behavioral research and the accepted and routine practice of medicine
2. The role of assessment of risk benefit criteria in the determination of the appropriateness of research involving human subjects
3. The nature and definition of informed consent in various research settings
4. Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research

II. Basic ethical principles relating to research involving human subjects

5. Kurt Baier, Ethical principles and their validity
6. Tom Beauchamp, Distributive justice and morally relevant differences
7. James Childress, The identification of ethical principles
8. H. Tristram Engelhardt, Jr., Basic ethical principles in the conduct of biomedical and behavioral research involving human subjects
9. Alvan R. Feinstein & Jeffrey L. Lichtenstein, Medical ethics and the architecture of clinical research
10. Alasdair MacIntyre, How to identify ethical principles
11. LeRoy Walters, Some ethical issues in research involving human subjects

III. Boundaries between research and practice

12. Donald T. Campbell & Joe Shelby Cecil, Protection of the rights and interests of human subjects in the areas of program evaluation, social experimentation, social indicators, survey research, secondary analysis of research data, and statistical analysis of data from administrative records
13. Donald Gallant, Response to Commission duties as detailed in P.L. 93-348, Sec. 202(a)(1)(B)(i)

14. Israel Goldiamond, On the usefulness of intent for distinguishing between research and practice, and its replacement by social contingency
15. Perry London & Gerald Klerman, Boundaries between research and therapy, especially in mental health
16. John Robertson, Legal implications of the boundaries between biomedical research involving human subjects and the accepted or routine practice of medicine
17. David Sabiston, The boundaries between biomedical research involving human subjects and the accepted or routine practice of medicine, with particular emphasis on innovation in the practice of surgery
18. Richard A. Tropp, What problems are raised when the current DHEW regulation on protection of human subjects is applied to social science research?

IV. Risk/Benefit criteria

19. Bernard Barber, Some perspectives on the role of assessment of risk/benefit criteria in the determination of the appropriateness of research involving human subjects
20. Gregory Kimble, The role of risk/benefit analysis in the conduct of psychological research
21. Maurice Natanson, A philosophical perspective on the assessment of risk-benefit criteria in connection with research involving human subjects
22. Lawrence C. Raisz, Essay on some problems of risk-benefit analysis in clinical pharmacology

V. Informed Consent

23. Diana Baumrind, Nature and definition of informed consent in research involving deception
24. Leonard Berkowitz, Some complexities and uncertainties regarding the ethicality of deception in research with human subjects
25. Albert Reiss, Jr., Selected issues in informed consent and confidentiality with special reference to behavioral/social science research/inquiry
26. Robert Veatch, Three theories of informed consent: philosophical foundations and policy implications

