Medical Research Summit
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INDEPENDENT IRBs

I. WHAT IS AN INDEPENDENT IRB?

A. Not part of a research institution

B. Organized to meet HHS and/or FDA IRB requirements

C. Reviews clinical research for the purpose of "protection of human subjects"

II. BASIS OF PROTECTION OF HUMAN SUBJECTS

A. Belmont Report

1. Respect for persons

2. Beneficence

3. Justice

B. Informed consent process

1. Information

2. Comprehension

3. Voluntariness

C. HHS Regulations

1. Protection of human subjects (Part 46)

2. Definitions (46.102)

a. IRB

b. IRB approval

3. IRB membership (46.107)

a. At least five members

b. Sufficiently qualified

4. IRB review of research (46.109)

5. General requirements for informed consent (46.116)

D. FDA Regulations

1. Institutional Review Board (Part 56)

2. Definitions (56.102)

a. IRB (56.102(g))

b. IRB approval (56.102(m))

3. IRB membership (56.107)

a. At least five members

b. Sufficiently qualified

4. IRB review of research (56.109)

5. Criteria for IRB approval of research (56.111)

III. CHANGES IN PHARMACEUTICAL RESEARCH

A. More research done outside of institutional setting

B. Greater involvement of practicing physicians

C. More research studies

D. Larger number of patients in studies

E. Multi-site research

IV. INSTITUTIONAL IRBs

A. Significant workload from institution

B. Reluctant to accept responsibility for research outside of institution

V. CREATION OF INDEPENDENT IRBs

A. Originally organized to meet FDA regulations

B. Sole focus of IRB Board is review of research

C. Focus of staff is complying with and obtaining information for initial and continuing review

VI. CONGRESSIONAL REVIEW OF IRB

A. Congressional hearing. "Institutional Review Boards: A System in Jeopardy?" Hearing before the Subcommittee on Human Resources, Committee on Government Review and Oversight, United States House of Representatives (June 11, 1998) Chairman: Rep. Christopher Shea

B. Dept. of Health and Human Services, Office of Inspector General's Report "Institutional Review Boards: A Time for Reform" June 1998 (OEI-01-97-00193)

C. Proposed legislation

1. Research Revitalization Act of 2002, S. 3060, 107th Cong., 2d Sess. (2002)

2. Human Research Subject Protections Act of 2002, H.R. 4697, 107th Cong., 2d Sess. (2002)

VII. ENFORCEMENT ISSUES

A. Office for Human Research Protections

B. Food and Drug Administration

VIII. ACCREDITATION PROGRAMS

A. Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRP)

B. National Committee for Quality Assurance (NCQA)

IX. THE FUTURE