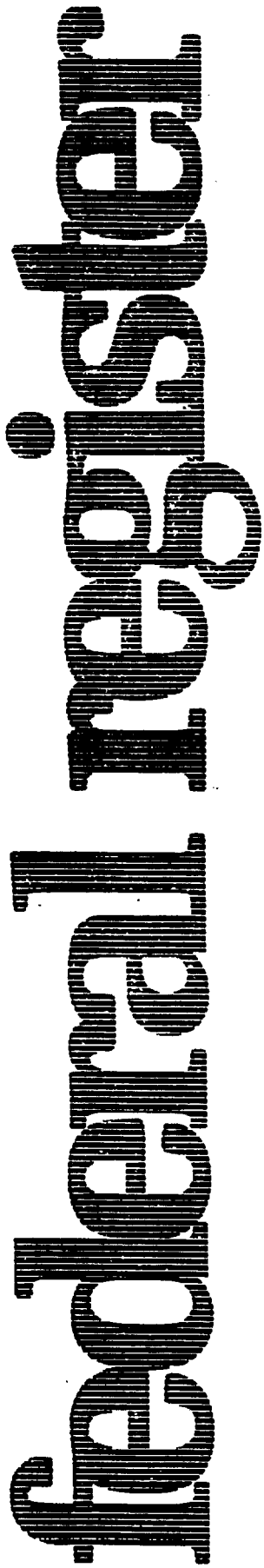

Tuesday
June 18 1991

Part II

Federal Policy for the Protection of Human Subjects; Notices and Rules

Office of Science and Technology Policy
Department of Agriculture
Department of Energy
National Aeronautics and Space Administration
Department of Commerce
Consumer Product Safety Commission
International Development Cooperation Agency
Agency for International Development
Department of Housing and Urban Development
Department of Justice
Department of Defense
Department of Education
Department of Veterans Affairs
Environmental Protection Agency
Department of Health and Human Services
Office of the Secretary
Food and Drug Administration
National Science Foundation
Department of Transportation

Approved For Release 2000/08/08 : CIA-RDP96-00789R003300220001-1

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Federal Policy for the Protection of Human Subjects

AGENCY: Office of Science and Technology Policy, Executive Office of the President.

ACTION: Notice of Federal Policy for Protection of Human Subjects.

SUMMARY: The Office of Science and Technology Policy has accepted the Final Federal Policy for the Protection of Human Subjects in the form of the common rule promulgated in this issue of the **Federal Register**. The common rule was developed by the Interagency Human Subjects Coordinating Committee of the Federal Coordinating Council for Science, Engineering and Technology, in response to public comment on the notice of proposed policy for Department and Agency Implementation published in the **Federal Register** on November 10, 1988 (53 FR 45660).

Note that the Central Intelligence Agency is required by Executive Order 12333 to conform to the guidelines issued by the Department of Health and Human Services (HHS).

ADDRESSES: Requests for additional information should be addressed to Dr. Joan P. Porter, Interagency Human Subjects Coordinating Committee, Building 31, room 5B59, Bethesda, Maryland 20892. Telephone: (301) 496–7005.

D. Allan Bromley,

Director, Office of Science and Technology Policy, Executive Office of the President.

[FR Doc. 91–14257 Filed 6–17–91; 8:45 am]

BILLING CODE 3170–01–M

DEPARTMENT OF AGRICULTURE

7 CFR Part 1c

DEPARTMENT OF ENERGY

10 CFR Part 745

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1230

DEPARTMENT OF COMMERCE

15 CFR Part 27

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1028

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

22 CFR Part 225

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 60

DEPARTMENT OF JUSTICE

28 CFR Part 46

DEPARTMENT OF DEFENSE

32 CFR Part 219

DEPARTMENT OF EDUCATION

34 CFR Part 97

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 16

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 26

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

NATIONAL SCIENCE FOUNDATION

45 CFR Part 690

DEPARTMENT OF TRANSPORTATION

49 CFR Part 11

Federal Policy for the Protection of Human Subjects

AGENCIES: United States Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency, Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; Department of Transportation.

ACTION: Final rule.

SUMMARY: This document sets forth a common Federal Policy for the Protection of Human Subjects (Model Policy) accepted by the Office of Science and Technology Policy and promulgated in regulation by each of the listed Departments and Agencies. A Proposed Federal Policy for the Protection of Human Subjects published November 10, 1988 (53 FR 45661) has been revised in response to public comments. The Policy as revised is now set forth as a common final rule. For related documents, see other sections of this **Federal Register** part.

EFFECTIVE DATE: These regulations shall become effective on August 19, 1991. The Department of Education regulations (34 CFR part 97) take effect either August 19, 1991, or later if Congress takes certain adjournments. If you want to know the effective date of the Department of Education regulations in 34 CFR part 97, call or write Mr. Edward Glassman, Office of Planning, Budget and Evaluation, U.S. Department of Education, room 3127, 400 Maryland Avenue SW., Washington, DC 20202–4132. A document announcing the effective date of the Department of Education regulations will be published in the **Federal Register**. Institutions currently conducting or supporting research in accord with Multiple Project Assurances of Compliance (MPAs) approved by and on file in the Office for Protection from Research Risks (OPRR) in the Department of Health and Human Services may continue to do so in accord with the terms and conditions of their MPAs. See Supplementary Information for further details.

FOR FURTHER INFORMATION CONTACT: Dr. Joan P. Porter, (301) 496–7005, Office for Protection from Research Risks, National Institutes of Health, Building 31, room 5B59, Bethesda, MD 20892.

SUPPLEMENTARY INFORMATION: Paperwork Reduction Act Requirements: Sections _____.103(a); _____.103(b); _____.103(b)(4)(i); _____.103(b)(4)(iii); _____.103(b)(5); _____.103(f); _____.109(d); _____.113; _____.115(a); _____.116; and _____.117 contain information collection requirements subject to approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. HHS has submitted the request for approval to OMB on behalf of all Departments and Agencies governed by this final rule and has published elsewhere in this issue of the **Federal Register** a request for OMB expedited review and approval of the information collection requirements. OMB has assigned OMB control number 9999–0020; however, the information collection requirements will not become effective until OMB has approved them. Unless a notice is published to the contrary, the public may assume that OMB has approved the information collection requirements during the 60-day period before the final rule becomes effective.

For further information regarding OMB approval of the information collection, contact Ms. Shannah Koss-McCallum, OMB, (202) 395–7316.

Compliance Dates: Institutions that hold MPAs are permitted and encouraged to apply all provisions of this final rule as soon as it is feasible to do so. They are urged not to wait for the negotiation and approval of a revised MPA to begin to function in accord with this rule. The OPRR, acting on behalf of the Secretary, Department of Health and Human Services (HHS), will continue to renegotiate and approve MPAs in the normal periodic cycle of renewal.

Institutions that are not operating under an MPA approved by OPRR will be required to negotiate an Assurance of Compliance with the supporting Department or Agency, prior to initiating research involving human subjects.

Institutions with MPAs approved by and on file with HHS will be allowed a "grace period" of sixty days after the

submission date for an application seeking HHS support, to provide certification of Institutional Review Board (IRB) review and approval. Exceptions may occur for reasons of Congressional mandate or special program or review requirements. In such cases, institutions will be advised that certification must be sent at an earlier time.

Background

This notice sets forth as a common rule requirements for the protection of human subjects involved in research conducted or funded by the following Federal Departments and Agencies: United States Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency, Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; National Science Foundation; Department of Health and Human Services and the Department of Transportation. Each of these Departments and Agencies have adopted the common rule as regulations to be codified as listed above.

The Food and Drug Administration (FDA) Final Rule to modify current regulations to conform to the Federal Policy are presented elsewhere in this issue of the **Federal Register**. Existing FDA regulations governing the protection of human subjects share a common core with the Federal Policy and implement the fundamental principles embodied in that policy. The agency is committed to being as consistent with the final Federal Policy as it can be, given the unique requirements of the Federal Food, Drug, and Cosmetic Act under which FDA operates; and the fact that FDA is a regulatory agency that rarely supports or conducts research under its regulations.

Adoption of the common Policy by Federal Departments and Agencies in regulatory form will implement a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research which was established on November 9, 1978, by Public Law 95–622. One of the charges to the President's Commission was to report biennially to the President, the Congress, and appropriate Federal Departments and Agencies on the protection of human subjects of biomedical and behavioral research. In carrying out that charge, the President's Commission was directed to conduct a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal Departments and Agencies regarding the protection of human subjects of biomedical or behavioral research which such Departments and Agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such Departments and Agencies, such review to include appropriate recommendations for legislation and administrative action.

In December 1981 the President's Commission issued its First Biennial Report on the Adequacy and Uniformity of Federal Rules and Policies, and their Implementation, for the Protection of Human Subjects in Biomedical and Behavioral Research, Protecting Human Subjects.

In accord with Public Law 95–622, each Federal Department or Agency which receives recommendations from the President's Commission with respect to its rules, policies, guidelines or regulations, must publish the recommendations in the **Federal Register** and provide an opportunity for interested persons to submit written data, views and arguments with respect to adoption of the recommendations. On March 29, 1982 (47 FR 13262–13305), the Secretary, HHS, published the recommendation on behalf of all affected Departments and Agencies.

In May 1982 the Chairman of the Federal Coordinating Council for Science, Engineering, and Technology (FCCSET) appointed an *Ad Hoc* Committee for the Protection of Human Research Subjects under the auspices of the FCCSET. The Committee, chaired by Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, Health and Human Services (HHS), was composed of representatives and ex-officio members of the affected Departments and Agencies. In consultation with the Office of Science and Technology Policy (OSTP) and the Office of Management and Budget, the *Ad Hoc* Committee, after considering all public comments, developed responses to the recommendations of the President's Commission. After further review and refinement, OSTP responded on behalf of all the affected Department and Agency Heads to the recommendations of the President's Commission, including the recommendation that:

> The President should, through appropriate action, require that all federal departments and agencies adopt as a common core the regulations governing research with human subjects issued by the Department of Health and Human Services (codified at 45 CFR Part 46), as periodically amended or revised, while permitting additions needed by any department or agency that are not inconsistent with these core provisions.

The *Ad Hoc* Committee agreed that uniformity is desirable among Departments and Agencies to eliminate unnecessary regulation and to promote increased understanding and ease of compliance by institutions that conduct federally supported or regulated research involving human subjects. Therefore, the *Ad Hoc* Committee developed a Model Federal Policy, which applies to research involving human subjects conducted, supported or regulated by Federal Departments and Agencies. In accordance with the Commission's recommendation, the Model Federal Policy is based on subpart A of the regulations of HHS for the protection of human research subjects (45 CFR part 46). The Proposed Model federal Policy developed by the *Ad Hoc* Committee was modified by OSTP to enhance uniformity of implementation among the affected Federal Departments and Agencies and to provide consistency with other related policies. The revised Model Federal Policy was concurred in by all affected Federal Departments and Agencies in March 1985.

An Interagency Human Subjects Coordinating Committee was chartered in October 1983 under the auspices of FCCSET to provide continued interagency cooperation in human subject research once the *Ad Hoc* Committee had completed its assignment. It is chaired by the Director of the Office for Protection from Research Risks, HHS, and composed of representatives of all Federal Departments and Agencies that conduct, support or regulate research involving human subjects. The Committee is advisory to Department and Agency Heads and, among other responsibilities, will evaluate the implementation of the Federal Policy and recommend modification as necessary.

On June 3, 1986, OSTP published for public comment in the **Federal Register** (51 FR 20204) a Proposed Model Federal Policy for Protection of Human Subjects and Response to the First Biennial Report of the President's Commission. Over 200 written comments were received concerning the publication. Th Interagency Human Subjects Coordinating Committee considered these comments in the revision of a common Federal Policy proposed as a common rule on November 10, 1988, for

adoption by each of the Departments and Agencies listed. Response to the more than 60 public comments, discussion of revisions made to that publication and the final common rule follow.

Summary of Public Comments Received in Response to the November 10, 1988, Federal Register publication (53 FR 45661) of the Notice of Proposed Common Rulemaking, Federal Policy for the Protection of Human Subjects for 16 Federal Departments and Agencies.

In response to the November 10, 1988, publication, 66 commentators responded within the comment period, which was extended to February 8, 1989. The source of comments included institutional offices of sponsored research, departmental deans and chairs and other staff of academic institutions, institutional review board members and staff, principal investigators, and drug company representatives. Although there were 66 separate commentators, several responses were prepared by organizations each representing a consortium of institutions which had been polled concerning the notice of proposed common rulemaking. For example, the Council on Governmental Relations, the Association of American Medical Colleges, Public Responsibility for Medicine and Research, Association of American Universities, the American Medical Association and the Consortium of Social Science Associations offered comment on behalf of their member institutions.

In general, commentators endorsed the efforts of the Office of Science and Technology Policy and the Federal Departments and Agencies to develop a Common Rule for the protection of human subjects.

The majority of the comments dealt with three points in the proposed common rule, as follows:

Section _____.103(b)(5) concerns those procedures set forth in Assurances of Compliance for research conducted or supported by a federal Department or Agency. As proposed, this section required that an Assurance should include:

> Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head (i) any unanticipated problems or scientific misconduct involving risks to human subjects or others (ii) any instance of serious or continuous noncompliance with this policy or the requirements of determinations of the IRB and (iii) any suspension or termination of IRB approval.

Some commentators indicated that they believed the proposed policy would inappropriately require IRBs to notify Department and Agency heads of scientific misconduct involving risks to human subjects and others and that the scientific fraud and misconduct regulations [September 19, 1988, Responsibilities of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science (53 FR 36344)] create duplicate and potentially conflicting requirements. Several suggested that the proposed rules on misconduct should leave undisturbed other existing regulatory schemes such as human subjects regulations of the Department of Health and Human Services at 45 CFR part 46. Other commentators indicated that the IRB should not have a "police" role and that its members are potentially legally liable if they did or did not report certain misconduct activities. Concern was also noted about additional responsibility and work placed on the IRB.

Several commentators requested clarification of § _____.103(b)(5)(i) in the terms "misconduct" and "unanticipated" problems. Respondents suggested that scientific misconduct implies falsification of data, plagiarism, abuse of confidentiality, dishonesty in presenting publications, legal violations and a range of other activities which should be addressed in a separate policy involving broader institutional considerations than those appropriate for an IRB. In addition, some respondents suggested that actual "harm" rather than "possible risk" to human subjects be reported to Departments and Agencies.

Concerning § _____.103(b)(5)(iii) two commentators suggested that IRBs would be reluctant to suspend IRB-approved research for administrative infractions (such as tardiness of response to an IRB) if such suspension must be reported to an Agency. One commentator requested that revisions be made so that only suspensions or terminations for serious or continuing noncompliance with the policy or determination of the IRB need be reported to the Department or Agency head. In that way, IRBs would use suspension or termination as a administrative tool and continue to keep Departments and Agencies informed of serious problems.

One specific set of comments addressed all aspects of this section by suggesting deletion of reporting requirements to Department and Agency Heads altogether. Rather, reports to IRBs and institutional officials would be required concerning unanticipated problems involving risks to human subjects which are substantial: proven scientific fraud; instances of substantial or continuing noncompliance with the policy or the requirements or determination of the IRB; or any suspension or termination which is more more than minor or temporary.

Response

In view of the comments and the policy concerning fraud and misconduct that is now under deliberation, the Interagency Human Subjects Coordinating Committee revised § _____.103(b)(5) as follows:

> Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

The President's Commission recommended in its 1981 *First Biennial Report* that institutional assurances should specify how "misconduct" should be reported and investigated (pp. 77–82, Recommendations 7 and 8). Since the time of the publication of the 1981 report, however, the issue of identification and reporting of misconduct has been deliberated in many other contexts and has included consideration of more than "misconduct involving risks to human subjects." In August 1989 the Department of Health and Human Services published a final rule announcing responsibilities of awardee and applicant institutions for dealing with and reporting possible misconduct in science [53 CFR 32446]. The Committee agrees that in the current context the inclusion of the term "misconduct" in the Federal Policy is confusing and misleading because other policy development efforts giving specific meaning to scientific misconduct are ongoing. Therefore, the term is deleted from this document.

The revised language is closer to that of the original provision in the Department of Health and Human Services regulations. The Interagency Committee wishes to clarify that it was never the intention of the Policy to require IRBs to report directly to Department and Agency Heads. Assurances of Compliance are negotiated between Departments or Agencies and awardee institutions. Assurances allow institutions to specify how reporting to Department and Agency Heads will take place. Reporting is the responsibility of the institutional official identified in each Assurance.

Further, the Committee wishes to clarify that "unanticipated problems" in this context includes serious and unexpected reactions to biologicals.

Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 2291. They are not classified as major because they do not meet the criteria for major regulations established under the Order.

Regulatory Flexibility Act Certification

The Secretary certifies that these interim final regulations will not have a significant economic impact on a substantial number of small entities.

The small entities that are affected by these interim final regulations are small institutions receiving research grants or contracts under the programs of the National Institute on Disability and Rehabilitation Research. However, the regulations do not have a significant economic impact on these entities because the regulations do not impose excessive regulatory burdens. These regulations impose minimal requirements that are necessary to ensure the proper treatment of handicapped children and mentally disabled persons under the programs of the National Institute on Disability and Rehabilitation Research.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding these interim final regulations. Comments are specifically invited on whether other research programs of the Department should have added protections for handicapped children and mentally disabled persons.

All comments submitted in response to these regulations will be available for public inspection, during and after the comment period, in room 3127, 400 Maryland Avenue, SW., Washington, DC between the hours of 9 a.m. and 4:30 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with the specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducng regulatory burden, the Secretary invites comment on whether there may be further opportunities to reduce any regulatory burdens found in these interim final regulations.

Assessment of Educational Impact

The Secretary has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects

34 CFR Part 350

Education, Education of the handicapped, Educational research, Grant programs—education.

34 CFR Part 356

Education, Education research, Fellowships.

(Catalog of Federal Domestic Assistance Number does not apply.)

Dated: June 6, 1991.

Lamar Alexander,

Secretary of Education.

The Secretary amends title 34 of the Code of Federal Regulations by amending parts 350 and 356 as follows:

PART 350—DISABILITY AND REHABILITATION RESEARCH: GENERAL PROVISIONS

3. The authority citation for part 350 continues to read as follows:

Authority: 29 U.S.C. 760–762, unless otherwise noted.

4. Section 350.3 is amended by revising paragraph (d) and the authority citation at the end of the section to read as follows:

§ 350.3 What regulations apply to these programs?

* * * * *

(d)(1) The regulations in 34 CFR part 97, PROTECTION OF HUMAN SUBJECTS, except § 97.107(a).

(2) Each Institutional Review Board (IRB) established under part 97 must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons knowledgeable in these areas. When an IRB reviews research that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects. If an IRB regularly reviews another vulnerable category of subjects, such an non-handicapped children, prisoners, pregnant women, or handicapped adults, consideration must also be given to the inclusion of one or more individuals who are knowledgeable about the experience in working with these subjects.

(Authority: 20 U.S.C. 761a, 762, 42 U.S.C. 300v-1(b))

PART 356—DISABILITY AND REHABILITATION RESEARCH: RESEARCH FELLOWSHIPS

1. The authority citation for part 356 continues to read as follows:

Authority: 29 U.S.C. 761a(d), unless otherwise noted.

2. Section 356.3 is amended by revising paragraph (c) and the authority citation at the end of the section to read as follows:

§ 356.3 What regulations apply to this program?

* * * * *

(c)(1) The regulations in 34 CFR part 97, PROTECTION OF HUMAN SUBJECTS, except § 97.107(a).

(2) Each Institutional Review Board (IRB) established under part 97 must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons knowledgeable in these areas. When an IRB reviews research that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects. If an IRB regularly reviews another vulnerable category of subjects, such as non-handicapped children,

drugs, or medical devices. Institutions have flexibility to establish channels of reporting to meet reporting requirements of Departments and Agencies. In addition, the Committee believes it is important that suspension or termination, for whatever reason, be reported to the Department and Agency Heads.

The Sixty Day "Grace" Period

Comment

The section of the proposed Policy and Final Rule eliciting the most comments was 103(f) regarding submission of certification. That section is as follows:

> Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §§ _____.101 (b) or (i). An institution with an approved assurance shall certify research covered by the assurance and by § _____.103 of this policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by § _____.103 of the policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

Most of the commentators (50) addressed the need for a grace period between the time of submission of an application for support to a Department and Agency and submission of certification by the IRB of review and approval of the proposal. A 60-day grace period was allowed in the previous Department of Health and Human Services Regulations for the Protection of Human Subjects. Under this provision, institutions with Multiple Project Assurances on file with HHS had sixty days to complete IRB review and approval and to notify HHS. This period of time roughly corresponded to the time between receipt of the application and initial scientific merit review. The groups evaluating the application for scientific merit need certification of the fact that an appropriate IRB has determined that human subject protections are adequate.

The commentators cited many reasons why a grace period is important for orderly institutional review and for protection of human subjects. Many of the comments on this section requested that the grace period be reinstated in the regulations. In brief, respondents noted that if the grace period is not allowed, investigators would be required to submit proposals to IRBs about two months earlier than at present. IRBs would be convened into emergency sessions or required to meet more frequently. Pressure to grant approval would increase.

Some commentators noted that institutions that have no Multiple Project Assurance on file with HHS are given 30 days to review and certify upon HHS request. If Multiple Project Assurance holders have no grace period, they may be at a disadvantage in time permitted for preparation and institutional review of their applications as compared to the time permitted institutions without a Multiple Project Assurance. Also, data for competitive renewals is often added just before submission to HHS so that the most current progress under the original award can be reported. If a grace period is not offered, applications may not contain information vital for appropriate peer review.

Another concern raised was that some researchers are required to modify their proposals several times before submission. The current 60-day period allows the IRB to review the final submission carefully.

One commentator indicated that the proposed provision was acceptable to the institution.

Response

Many Federal Departments and Agencies do not have application review schedules that correspond to those of HHS. A 60 day grace period is without relevance to their review systems. At the time of publication of the proposed common rule, the Interagency Committee noted that HHS intended to retain a "grace period" for institutions that have Multiple Project Assurances and announce the period through advisories that are routinely received by institutions. HHS has carefully considered the public comments and will ordinarily retain the 60-day grace period in its administrative procedures. In some programs, such as AIDS-related research, HHS has modified the receipt and review schedules in accordance with a Congressional mandate.

The Departments and Agencies, other than HHS, adopting the common rule are aware of the concerns of the institutions and will provide as much flexibility to IRBs as possible in the orderly processing of applications for support. To require a 60-day grace period or any standard grace period for all Departments and Agencies would require far-reaching changes in the review and processing systems of these organizations. Institutions will be advised of Department and Agency procedures through routine publications. Consequently, the language in the final rule remains unchanged.

Composition of the IRB

Comments

Section _____.107 of the Policy deals with composition of the IRB. Several points made by commentators are as follows:

In § _____.107(a) there is the requirement that if an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. The HHS regulations at 45 CFR part 46 promulgated in 1981 utilized a different standard, i.e., "if an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other subparts of [45 CFR part 46], the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects." The commentator indicated that his institution would retain previous standards, because advocates for special populations have been of great benefit in the IRB's decision-making process.

Another commentator wrote that in her institution, full committee review is required when a vulnerable population is involved; all committee members are advocates for subjects whether or not they themselves are involved in a vulnerable population. Adding new members would make the committee too large to be workable, she wrote.

The majority of the comments on this section were directed to the departure proposed by the Department of Education at 34 CFR part 97.107(a). The proposed departure was based on a concern for protection of mentally disabled persons and handicapped children. The departure would have provided that, for research conducted o. supported by the Department of Education," when an IRB reviews research that deals with handicapped children or mentally disabled persons, the IRB shall include at least one person primarily concerned with the welfare of the research subject." The remainder of the departure reiterated the common

rule's provision which required institutions to consider representation on the IRB of persons who are knowledgeable about and experienced in working with certain vulnerable subjects if the IRB regularly reviews research involving those vulnerable subjects. Twenty-one institutions commented on this proposed departure. The majority of these comments were opposed to the proposed departure.

Some commentators, while supporting the proposed language in § _____.107, stated their belief that the departure was not necessary because the policy in § _____.107 already addresses representation of the special concerns of vulnerable subjects on the IRB. Thus, the rights of handicapped children and mentally disabled persons should be represented on any IRB that regularly reviews proposals involving those individuals, and there is no constructive advantage to emphasizing these two categories of subjects. Such an emphasis was seen as a precedent with the potential for discrimination against other categories of vulnerable subjects. When special expertise is required, IRBs already have the option and the obligation to seek informed consultants, respondents noted. One commentator stated, however, "If in future staffing of our IRB, someone with expertise in this area is available and willing to serve, we would be happy to encourage such participation."

Some commentators objected to the lack of consistency among Federal Departments and Agencies and cited the Department of Education's proposed departure as being inconsistent with the purpose of the common rule.

One commentator suggested that only when the IRB regularly reviews research that deals with handicapped children or mentally disabled persons should the IRB include at least one person primarily concerned with the welfare of the research subjects. Otherwise, consultation should take place when appropriate. Another suggestion was that handicapped children and mentally disabled persons be added to the list of examples of vulnerable subjects for which an IRB that regularly reviews research might want to consider inclusion of one or more members who are knowledgeable about and experienced in working with these subjects.

Response

The Department of Education has considered these comments carefully and has decided to withdraw the departure to the common rule and to adopt the common rule as promulgated in this document. The Secretary, however, continues to believe that there is a special need to protect handicapped children and mentally disabled persons. Thus, the Secretary strongly urges institutions to included at least one person who is primarily concerned with the welfare of the research subjects whenever the research involved handicapped children or mentally disabled persons. While the Secretary agrees to the common rule provision regarding IRB representation as a general matter, the Secretary has decided to address the concerns underlined by the proposed departure on a programmatic basis under the Department of Education's programs of the National Institute on Disability and Rehabilitation Research (34 CFR parts 350 and 356). Accordingly, the Secretary amends the program regulations for these programs in a document published in another section of this **Federal Register** part.

In light of the concern of the Department of Education that these groups were not clearly identified as vulnerable populations, "handicapped" has been added to the illustrative list in § _____.107.

Comments on Other Sections

Section _____.101 explains the application of the Policy. Section _____.101(b) describes categories of research that are exempt from the Policy.

Comment

Several commentators indicated that the language and intent of this section was helpful. One commentator indicated that he believes the section was written primarily for medical and health research and should not apply to involvement of human subjects for general business interviews or surveys. The commentators recommended the exemption of information gathering related to business. Further comment suggested that all minimal risk research be exempt from the regulations.

Response

The Committee believes that the exemptions are sufficiently clear so that all types of research, not just biomedical or health research, may be reviewed using the specified criteria. In addition, the Committee has indicated that the exemptions of § _____.101(b) of the Policy provides for the exemption of certain research including much of the research used by business (e.g., survey research) in which there is little or no risk.

Section _____.101(b)(2)

Comment

Section _____.101(b)(2) is an exemption for research involving the use of educational tests, survey procedures or observation of public behavior. To paraphrase, this type of research is exempt unless information is recorded in a manner such that subjects can be identified and disclosure of the responses outside the research could place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Three commentators expressed concern that the additional subparts B, C, and D of the HHS regulations for the protection of human subjects are not part of the Federal policy. They noted that institutions with assurances with HHS will be required to apply provisions of those subparts in research they support or conduct, while other Federally-supported research would not be subject to the subpart requirements.

Others commenting on § _____.101(b)(2) indicated that research that could involve sensitive data could place the subjects at risk, even if information is not recorded in such a manner that human subjects can be identified and should not be exempt from provisions of the Policy. One respondent noted that one IRB reviews this type of research even if an exemption is permitted by the regulations. Another indicated that this section will exclude from normally exempt educational, survey, interview or observational research any instances wherein disclosure of subjects responses could be damaging to the subject's reputation. Because reputation is a subjective term that is difficult to define operationally, the commentator suggested that the wording be changed to limit exceptions to specific risks of "professional and sociological damage."

Response

The Interagency Committee may at a later date wish to consider incorporation or provisions of the other subparts of the HHS regulations into federal policy. However, such considerations should not delay publication of basic protections for all human subjects. At this time, institutions sponsoring research under HHS-approved assurances will adhere to provisions of all the subparts of 45 CFR part 46. A footnote has been added to § _____.101(b) indicating that

Institutions with HHS-approved assurances on file will abide by provisions of 45 CFR 46 subparts A–D. Some of the other

Departments and Agencies have incorporated all provisions of 45 CFR 46.101(b) into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption at 45 CFR 46.101(b)(2) for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

A Notice to amend subpart D, 45 CFR 46.401(a)(2)(b) to renumber exemptions to permitted and not permitted to conform the subpart D reference to the renumbered exemptions in the Common Rule is published elsewhere in this issue of the **Federal Register.**

Under this footnote, for research involving children, institutions that have multiple project assurances on file with OPRR will not be able to use all provisions in the exemption in § _____.101(b)(2). However, the educational tests basis for the exemption contained in § _____.101(b)(2) will still be available to institutions conducting research involving children. In developing the common rule, a number of HHS exemptions were consolidated, including the HHS educational tests exemption. The educational tests exemption has been available for use under subpart D of the HHS regulations, Additional Protections Involving Children. Thus, the footnote to the common rule continues the provision that existed under the previous regulations.

Some institutions do not choose to permit exemptions even if they are permitted by the policy. This is their prerogative, and assurances of compliance incorporate provisions for utilizing exemptions.

Section _____.101(b)(3)

Comment

Section _____.101(b)(3) described an exemption for research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is not exempt under the exemption in § _____.101(b)(2) if human subjects are elected or appointed public officials or candidates for public office or if Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. Two commentators recommended deletion of this exemption because confidentiality considerations are not the only purpose of IRB review. Other human subjects protections issues might need to be considered in research that is not exempt by the criteria described in § _____.101(b)(2). Furthermore, the commentators explained that IRBs and institutions will not know that Federal statutes afford these protections, and inconsistency and confusion is likely.

Response

At present the only statutes that meet the criteria in § _____.101(b)(3)(ii) of which the Committee is aware are those for research conducted or supported by the Department of Justice under 42 U.S.C. 3789g, and certain research conducted or supported by the National Center for Education Statistics of the Department of Education under 20 U.S.C. 1221e–1. The Department of Justice's Office of Justice Programs (OJP) has several constituent offices that conduct research that would fall under § _____.101(b)(3). The law governing OJP research activities, 42 U.S.C. 3789g(a), provides that

> Except as provided by Federal law other than this chapter, no officer or employee of the Federal Government, and no recipient of assistance under the provisions of this chapter shall use or reveal any research or statistical information furnished under this chapter by any person and identifiable to any specific private person for any purpose other than the purpose for which it was obtained in accordance with this chapter. Such information and copies thereof shall be immune from legal process, and shall not, without the consent of the person furnishing such information, be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceedings.

The law governing research conducted by the National Center for Education Statistics under 20 U.S.C. 1221e–1 provides that data collected by the National Center for Education Statistics may not be used for any purpose other than the statistical purpose for which the data were collected and establishes further protections regarding that data, including a provision that they

> shall be immune from legal process, and shall not, without the consent of the individual concerned, be admitted as evidence or used for any purpose in any action, suit, or other judicial or administrative proceeding. 20 U.S.C. 1221e–1(d)(4)(B).

It is the responsibility of a Federal Department or Agency to assist the institutions proposing to conduct a research project which it supports in determining if the research is subject to the provisions of the Federal statutes meeting the criteria in § _____.101(b)(3)(ii).

Section _____.101(h)

Comment

Section _____.101(h) discusses research that takes place in foreign countries covered by the policy. One respondent endorsed this section. Another found the provision somewhat ambiguous and suggested that it be made clear that a researcher may either comply with the policy provision or may substitute the foreign procedure in lieu of the policy only following a determination by the Department or Agency Head that the foreign procedures are at least equivalent to those required in the policy. Another comment reflected that it may be difficult at the time of submitting a research proposal to a supporting Department or Agency to know if a foreign country's guidelines provide protections which are at least equivalent to the policy; the Interagency Committee or Department or Agency Heads should publish regulations or advisories indicating which are considered "equivalent."

Response

The Interagency Committee concurs that evaluation of other country's protection requirements in comparison with the policy will be an important Committee initiative and it will consider publication of notices that reflect the decisions of Department and Agency Heads.

Also in § _____.101(h), reference to Helsinki as amended in 1983 is now changed to Helsinki as amended in 1989.

Section _____.102 Definitions

Comment

Section _____.102 includes the definition section in the Federal Policy. In this section, one commentator asked for a definition of "principal investigator," since that individual bears responsibility for human subject protection. Another commentator suggested adding a definition of "scientific fraud."

Another suggestion was to take into account First Amendment concerns involving freedom of speech in situations where social scientists interview foreign and domestic government and private individuals to obtain information. Another commentator suggested that the definition of human subject in § _____.102(f) should make clear that with, respect to interview research, a distinction should be made between

information provided by a person which relates to past or present events or the actions of others, as opposed to the attitudes or actions of the interviewees themselves: only in the latter case should the interviewee constitute a human subject. Also, another letter explained that in some cultures, ancestral research would not come under the definition of "human subject" because individuals were deceased. However, this type of research might be distressing to living family members.

Section _____.102(b) includes the definition of "institution." One commentator proposed that the definition of "private entity" should also be included.

Section _____.102(h) includes the definition of "IRB approval." Three commentators suggested that the term "at the institution" was not appropriate in the definition of approval as "* * * determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements." Much of the research of an institution is off-site and thus seemed to be in technical violation under the proposed language.

Response

The Interagency Committee agrees that the principal investigator is a key person for protection of human subjects and bears a broad responsibility for implementation of the requirements. The term "investigator" is used in the policy, but not "principal investigator" and no definition is provided because the responsibility for protecting human subjects is shared by the entire research team. No definition of scientific fraud has been included, and the term has been deleted from § _____.103(b)(5), as described previously.

The Committee believes that the comment on § _____.102(f), definition of "human subject," about interview content is addressed through application of exemption criteria in § _____.101(b)(2) as well as in the precise wording of the definition itself.

In response to the comments about the phrase "at the institution" in the definition of IRB approval in § _____.102(h), the Interagency Committee responds that there are instances in which the IRB has approval authority where the research is not conducted at the institutional site. The policy at § _____.114, Cooperative Research, is an important cross-reference.

Establishment and approval of other off-site IRBs may be required in some circumstances in which another institution is involved in research. The Department or Agency Heads reserve the authority to approve cooperative arrangements. The phrase "at the institution" in the definition of IRB approval should be interpreted to mean field sites and other off-site facilities over which an institution has jurisdiction.

Section _____.103 Assurances

Comment

Section _____.103 explains how compliance is assured under this Policy in research conducted or supported by a federal Department or Agency. Most of the comments on this section concerned reporting and misconduct issues in § _____.103(b)(5) or the "grace period" or timing of certification in § _____.103(f), discussed previously. Several other comments are as follows: Three respondents asked for clarification of the rationale for reporting requirements in § _____.103(a). This section requires that when the existence of an HHS-approved assurance is accepted in lieu of requiring submission of a new assurance, reports required by the Policy are to be made to the Department and Agency Heads. Reports (with the exception of certification) are also to be made to OPRR.

Another comment was prompted by review of § _____.103(b)(1) which requires inclusion in the assurance of principles governing the institution in protection of human subjects, such as a statement of ethical principles or existing codes. The commentator suggested that a statement as to the purpose of having regulations which create an IRB structure should be explicitly included in the regulations.

A comment concerning § _____.103(f) requests clarification on what type of certification documentation will be acceptable.

Response

In consideration of these comments, the Interagency Committee offers the following information. In § _____.103(a) the only reports required to be made to both the head of the Department or Agency supporting the research and the OPRR when the HHS assurance is utilized are those required under § _____.103(b)(5). The head of the Department or Agency supporting a research project must have information concerning conduct of that research including instances of unanticipated problems or serious or continuing noncompliance with the Policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval. OPRR requires this information to ensure that human subjects protections under the Policy and under the HHS-approved Assurance are being properly implemented and that institutions have fulfilled their requirements in an appropriate and timely manner.

With regard to the comment concerning certification requirements in § _____.103(f), standardized language for the certification will be developed. Certification now used by HHS has been suggested as a basis for development of the language.

Section _____.107 IRB Membership

Comment

Most of the commentators on § _____.107 address the proposed departure on IRB membership for the Department of Education that has been discussed above [§ _____.107(a)]. Other comments received were as follows: Reference is made in the Policy in several places to vulnerable subject populations. One commentator indicated that all subject populations are vulnerable and that the term "exceptionally vulnerable" would be better phraseology for those instances for which additional safeguards are urged or required.

Section _____.107(b) requires that every reasonable nondiscriminatory effort be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes. One respondent indicated that the HHS standard in the regulations published in 1981 requiring that no IRB shall be constituted entirely of men or entirely of women should be retained. A further requirement of § _____.107(b) is that no IRB may consist entirely of members of one profession. Another respondent suggested that the word "discipline" be substituted for "profession."

Response

The Committee did not believe that the suggested language changes would significantly improve the understanding or implementation of the sections. It expects that institutions will use good judgment and diligence in selecting persons as IRB members who can fulfill the requirements of § _____.107 (a) and (b) so that persons of both genders and persons with varying backgrounds will promote responsible review of the research activities. In approving Assurances, the Federal Departments and Agencies that conduct, support or regulate research will review IRB

composition to ensure that the membership is appropriate for the research, and may request that membership be supplemented if complete and adequate review of the research does not appear possible.

As regards the gender consideration in IRB composition the Committee notes that in seeking diverse membership on the IRB, the institution must consider both men and women who can contribute to the role of the IRB.

Section _____.110 Expedited Review Procedures

Comment

This section sets forth expedited review procedures for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Section _____.110(b) indicates that an IRB may use the expedited review procedure under certain specified circumstances with the approval of Department or Agency heads. Four respondents noted that confusion may result in institutions if Departments or Agencies have different requirements. Furthermore, it may be burdensome to IRBs and institutions to seek Department and Agency approval for use of expedited review. One respondent recommended that the phrase "with the approval of department or agency heads" in § _____.110(b) be deleted because it will result in bureaucratic delays in approval to use the authority. Furthermore, the authority to restrict use of expedited review is found in § _____.110(d) whereby the Department or Agency head may restrict, suspend, terminate or choose not to authorize the use of the expedited review procedure.

Response

The Committee agreed that the phrase in § _____.110(b) "with the approval of department or agency heads," should be deleted because § _____.110(d) accomplished the intention of the Committee. As an example of Department and Agency use of this authority, note that HHS does not permit expedited review for institutions that do not hold Multiple Project Assurances of Compliance. Note also that some institutions which have authority to use expedited procedures choose to use full IRB review instead.

Note that parentheses have been added to the word "reviewer(s)" in § _____.110(b)(1) to clarify that one or more reviewers may carry out the expedited review procedures in accordance with § _____.110(b).

Section _____.111 Criteria for IRB Approval of Research

Comment

Three commentators requested deletion of the term "economically or educationally disadvantaged" in the examples of those who are vulnerable subjects because of lack of clarity of the term, difficulty in determining if some subjects were in this category and possible exclusion from beneficial research protocols of those deemed to be included in this category.

Response

The Committee believes that the criteria for participation and the potential vulnerability of some research subjects are still a very important consideration for IRBs. In exercising their responsibilities, IRBs are charged with evaluating the benefits and the burdens of the research so that unjust social patterns do not appear in the overall distribution of the burdens and benefits of research. The 1979 Belmont Report outlining ethical principles and guidelines for the protection of human subjects of research written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research makes special note that some populations are burdened in many ways by their social circumstances and environments.

> * * * when research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called on first to accept these risks of research, except where research is directly related to the specific conditions of the class involved.
>
> * * * certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

The Committee expects that in its review of equitable treatment and review of benefits and burdens, the educationally or economically disadvantaged will not be excluded from potentially beneficial research to individuals or to those persons as a class.

Section _____.113 Suspension or Termination of IRB Approval of Research

Comment

One comment was offered suggesting that institutions, not IRBs, should report to Department and Agency Heads. Another response recommended that OPRR be designated as the central coordinating office to which such notification should be sent. Designation of OPRR as the single reporting channel would ensure prompt requisite reporting to the Government, the commentator noted.

Response

This section does not require that the IRB report to the Department or Agency head. The responsibility for reporting is specified in the institution's assurance.

OPRR will receive reports if institutions have an assurance on file with the HHS which covers the research in question and will be notified in accordance with § _____.103(b)(3). OPRR cannot act as a central information office for other Departments and Agencies in receiving reports of this nature because of insufficient resources and regulatory jurisdictional considerations.

Section _____.114 Cooperative Research

Comment

Confusion may result for institutions if Departments and Agencies have differing requirements.

Response

The Committee will attempt to advise Departments and Agencies so that procedural requirements will be consistent.

Section _____.115 IRB Records

Comment

Modified language for this section was suggested to assure that confidentiality will be maintained to the greatest extent possible.

Response

The Committee agreed that confidentiality considerations are most important for IRB records. While it rejected the detailed language suggested by the commentator, it acknowledged the importance of maintaining confidentiality. It believes that the proposed language is adequate.

Section _____.116 General Requirements for Informed Consent; and

Section _____.117 Documentation of Informed Consent

Comment

One respondent wrote that the differences between §_____.116 (c) and (d) and §_____.117(c) were confusing.

Response

Section _____.116(c) specifies that an IRB may approve a consent procedure which alters some or all of the required elements of informed consent or waives the requirement to obtain informed consent in research or demonstration projects which are subject to approval of state and local authorities and which meet certain other requirements. Section _____.116(d) specifies that an IRB may, under limited circumstances [other than those of §_____.116(c)] approve a consent procedure which alters some or all of the elements of informed consent or waive the requirements to obtain informed consent for certain types of research. Section _____.117(c) specifies conditions under which an IRB may waive the requirement for the investigator to obtain a signed consent document for some or all subjects in the research.

Section _____.123 Early Termination of Research

Comment

Two commentators expressed concern the establishment of this section implies that a "blacklist" composed of individuals and institutions that, in the judgment of Department and Agency Heads, have failed to discharge properly their responsibilities for the protection of human subjects. Serious breaches of confidentiality and due process could be implied. The inclusion of the parenthetical phrase "(whether or not the research was subject to federal regulations)" was also of concern because it implies that information gathering may lead to violations of confidentiality.

Response

The Committee is aware of concerns about the need for confidentiality and due process considerations. The Committee notes that other federal regulations deal with the suspension and termination of funding. These regulations provide the requisite due process. Sources of information and criteria to be used by Department and Agency Heads for making decisions are addressed with more specificity in those regulations. The federal government does maintain information that is pertinent to the exercise of the discretionary authority to award funding. Appropriate confidentiality protections apply to that information.

Section _____.124 Conditions

Comment

A suggestion was made that additional considerations of the Department or Agency head noted in this section should be limited to those required by statute.

Response

The Committee, in its ongoing deliberations, will attempt to maintain consistency and minimize burdens to institutions.

Department and Agency—Specific Comments

Department of Education

The 34 CFR 97.107(a) departure on composition of the IRB was discussed earlier in this preamble.

The Department of Education proposed to amend §_____.101(b)(3), To what does this policy apply, by revising paragraph (b)(3)(ii) to exempt educational tests and surveys, interviews, or certain observations from coverage of the regulations if the research is conducted under a program subject to the protections of the General Education Provisions Act (GEPA). This departure would have expanded upon an exception contained in the common rule that exempted research conducted under a statute that requires that the confidentiality of the personally identifiable information be maintained, without exception, throughout the research and thereafter.

Much of the research that would have been covered by the GEPA exception is conducted by the National Center for Education Statistics (NCES). Since publication of the NPRM for the common rule, the Department has developed procedures implementing new authority under GEPA that establish absolute confidentiality for individuals who are the subjects of the NCES research which is subject to the confidentiality requirements of section 406(d)(4) of GEPA. Thus, NCES research covered by the GEPA confidentiality requirements now falls within the exception in the common rule that excludes from coverage of the regulations research under a statute that provides for absolute confidentiality [§_____.101(b)(3)(ii)] and an expanded exception for that research is unnecessary.

The Secretary has decided to withdraw the GEPA departure as being inconsistent with the Department's overall objective of ensuring that research conducted or sponsored by the Department contain the greatest possible protections consistent with the common rule. Research of the Department other than that conducted under the NCES statute will be covered by the common rule.

Comment

Four comments were received regarding the exception from the common rule requirements for programs covered by GEPA. Three of the commentators were concerned that the proposed departure removed safeguards or did not provide additional safeguards for the protection of research subjects, while possibly increasing administrative burden on IRBs. One of these three commentators was concerned that the proposed departure might prohibit certain research procedures as applied to educational practices or programs. One commentator indicated that the proposed departure would not pose any problems.

Response

The departure to §_____.101(b)(3)(ii) was based on statutes applicable to the Department that provide protection for subjects of the Department's education-related tests and surveys, interview procedures, and observation of public behavior. The protections are found in the GEPA at section 400A (control of paperwork) (20 U.S.C. 1221–3); section 406(d)(4) (confidentiality of National Center for Education Statistics data) (20 U.S.C. 1221e–1); section 438 (Family Educational Rights and Privacy Act) (20 U.S.C. 1232g); and section 439 (Protection of Pupil Rights Amendment) (20 U.S.C. 1232h). The departure was not intended to create additional burdens for IRBs but to eliminate the need for IRB approval of research in those cases where the research was subject to the GEPA. The Secretary has withdrawn the proposed departure because it is inconsistent with ensuring the greatest protection under the programs administered by the Department.

Because the departure is being withdrawn, there is no need to explain how the proposed departure would have affected research practices.

Department of Veterans Affairs (VA)

Concern was expressed that §_____.111(a)(4) and §_____.116 of

the Federal Policy would supersede the Veterans Administration Department of Medicine and Surgery (VA DM&S) Circular 10–88–50 which allows next of kin to grant consent for incompetent relatives under specific conditions.

The VA responded, however, that Federal Policy mandates informed consent by the subject, or the subject's "legally authorized representative." "Legally authorized representative" is defined to include "individual(s) * * * authorized under applicable law * * * to consent on behalf of a prospective subject * * *." Thus, the proposed consent does not preclude next of kin consent so long as such consent is "authorized under applicable law."

38 U.S.C. 4131, and VA policies promulgated thereunder, do authorize next of kin consent. Accordingly, the Common Federal Policy and current VA policies are consistent.

Department of Justice

The Department of Justice intends to retain special protections for prison populations in research it supports or conducts in accordance with 28 CFR parts 22 and 512.

Department of Defense

Comment

One response requested clarification of how the Federal Policy will extend to DOD research. Numerous questions concerning applicability to military and non-military personnel, voluntary versus mandated participation situations, identifiable data and the broad range of DOD-sponsored research were posed. The respondent indicated that formulating guidelines for informed consent is particularly important in the military context.

Response

Questions raised regarding application of the proposed regulations to DOD-supported research are reasonable and appropriate but are regarded as agency specific. DOD plans to address these particular issues through revision of DOD Directive 32–16.2, Protection of Human Subjects in DOD-supported Research.

The text of the common rule is adopted by the following Department and Agencies as set forth below:

Text of the Common Rule

The text of the Common Rule as adopted by the Department and Agencies in this document appears below:

_____CFR Part _____—Protection of Human Subjects

Sec.

§ ____.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § ____.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § ____.102(e) must be reviewed and approved, in compliance with § ____.101, § ____.102, and § ____.107 through § ____.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department of agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the **Federal Register** or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, Department of Health and Human Services (HHS), and shall also publish them in the **Federal Register** or in such other manner as provided in department or agency procedures.[1]

§ ___.102 **Definitions.**

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

(2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of

[1] Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A–D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR part 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption at 45 CFR part 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§ ___.103 Assuring compliance with this policy—research conducted or supported by any federal department or agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Protection from Research Risks, HHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under § ___.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with § ___.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, HHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under § ___.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by § ___.03 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by § ___.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution. (Approved by the Office of Management and Budget under Control Number 9999–0020.)

§ ___.104 [Reserved]

§ ___.105 [Reserved]

§ ___.106 [Reserved]

§ ___.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly

conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ ____.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in § ____.103(b)(4) and, to the extent required by, § ____.103(b)(5).

(b) Except when an expedited review procedure is used (see § ____.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ ____.109 IRB Review of Research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § ____.116. The IRB may require that information, in addition to that specifically mentioned in § ____.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § ____.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under Control Number 9999–0020.)

§ ____.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the **Federal Register**, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the **Federal Register**. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk.

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § ____.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§ ____.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the

possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § ____.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § ____.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ ____.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ ____.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

(Approved by the Office of Management and Budget under Control Number 9999–0020.)

§ ____.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ ____.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § ____.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in § ____.103(b)(4) and § ____.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § ____.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner. (Approved by the Office of Management and Budget under Control Number 9999–0020.)

§ ____.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consis of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will

involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4)The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law. (Approved by the Office of Management and Budget under Control Number 9999–0020.)

§ ____.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § ____.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § ____.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. (Approved by the Office of Management and Budget under Control Number 9999–0020.)

§ ____.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subject's involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § ____.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ ____.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency,

and final approval given to the proposed change by the department or agency.

§ ___.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a federal department or agency.

The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ ___.121 [Reserved]

§ ___.122 Use of federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ ___.123 Early termination of research support; evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragarph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ ___.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

DEPARTMENT OF AGRICULTURE

7 CFR Part 1c

RIN 0518-AA00

List of Subjects in 7 CFR Part 1c

Human subjects, Research, Reporting and record keeping requirements, Title 7 of the Code of Federal Regulations is amended by adding part 1c as set forth at the end of this document.

PART 1c PROTECTION OF HUMAN SUBJECTS

Sec.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b)

Dated: December 13, 1990.

Charles E. Hess,

Assistant Secretary, Science & Education.

DEPARTMENT OF ENERGY

10 CFR Part 745

RIN 1901-AA13

List of Subjects in 10 CFR Part 745

Human subjects, Research, reporting, and Record-keeping requirements. Title 10 of the Code of Federal Regulations is amended by revising part 745 as set forth at the end of this document

PART 745 PROTECTION OF HUMAN SUBJECTS

Sec.

Authority: 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v-1(b).

Dated: December 21, 1990.
James D. Watkins,
Secretary of Energy.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1230

RIN 2700-AA76

List of Subjects in 14 CFR Part 1230

Human subjects, Research, Reporting and Record-keeping requirements. Title 14 of the Code of Federal Regulations is amended by adding part 1230 as set forth at the end of this document.

PART 1230 PROTECTION OF HUMAN SUBJECTS

Sec.
1230.101 To what does this policy apply?
1230.102 Definitions.
1230.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
1230.104 [Reserved]
1230.105 [Reserved]
1230.106 [Reserved]
1230.107 IRB Membership.
1230.108 IRB functions and operations.
1230.109 IRB review of research.
1230.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
1230.111 Criteria for IRB approval of research.
1230.112 Review by institution.
1230.113 Suspension or termination of IRB approval of research.
1230.114 Cooperative research.
1230.115 IRB records.
1230.116 General requirements for informed consent.
1230.117 Documentation of informed consent.
1230.118 Applications and proposals lacking definite plans for involvement of human subjects.
1230.119 Research undertaken without the intention of involving human subjects.
1230.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
1230.121 [Reserved]
1230.122 Use of Federal funds.
1230.123 Early termination of research support: Evaluation of applications and proposals.
1230.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: January 21, 1991.
Richard H. Truly
Administrator.

DEPARTMENT OF COMMERCE

15 CFR Part 27

RIN 0690-AA17

List of Subjects in 15 CFR Part 27

Human subjects, Research, Reporting and recordkeeping requirements. Title 15 of the Code of Federal Regulations is amended by adding part 27 as set forth at the end of this document.

PART 27 PROTECTION OF HUMAN SUBJECTS

Sec.
27.101 To what does this policy apply?
27.102 Definitions.
27.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
27.104 [Reserved]
27.105 [Reserved]
27.106 [Reserved]
27.107 IRB Membership.
27.108 IRB functions and operations.
27.109 IRB review of research.
27.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
27.111 Criteria for IRB approval of research.
27.112 Review by institution.
27.113 Suspension or termination of IRB approval of research.
27.114 Cooperative research.
27.115 IRB records.
27.116 General requirements for informed consent.
27.117 Documentation of informed consent.
27.118 Applications and proposals lacking definite plans for involvement of human subjects.
27.119 Research undertaken without the intention of involving human subjects.
27.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
27.121 [Reserved]
27.122 Use of Federal funds.
27.123 Early termination of research support: Evaluation of applications and proposals.
27.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: December 21, 1990.
Robert Mosbacher,
Secretary of Commerce.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1028

RIN 3041-AA95

List of Subjects in 16 CFR Part 1028

Human subjects, Research, Reporting and recordkeeping requirements. Title 16 of the Code of Federal Regulations is amended by revising part 1028 as set forth at the end of this document.

PART 1028 PROTECTION OF HUMAN SUBJECTS

Sec.
1028.101 To what does this policy apply?
1028.102 Definitions.
1028.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
1028.104 [Reserved]
1028.105 [Reserved]
1028.106 [Reserved]
1028.107 IRB Membership.
1028.108 IRB functions and operations.
1028.109 IRB review of research.
1028.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
1028.111 Criteria for IRB approval of research.
1028.112 Review by institution.
1028.113 Suspension or termination of IRB approval of research.
1028.114 Cooperative research.
1028.115 IRB records.
1028.116 General requirements for informed consent.
1028.117 Documentation of informed consent.
1028.118 Applications and proposals lacking definite plans for involvement of human subjects.
1028.119 Research undertaken without the intention of involving human subjects.
1028.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
1028.121 [Reserved]
1028.122 Use of Federal funds.
1028.123 Early termination of research support: Evaluation of applications and proposals.
1028.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: January 11, 1991.

Sheldon D. Butts,

Acting Secretary.

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY, AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 225

RIN 0412-AA17

List of Subjects in 22 CFR Part 225

Human subjects, Research, Reporting and record-keeping requirements. Title 22 of the Code of Federal Regulations is amended by adding part 225 at set forth at the end of this document.

PART 225 PROTECTION OF HUMAN SUBJECTS

Sec.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Dated: December 13, 1990.

Richard E. Bissell,

Assistant Administrator for Science and Technology.

Department of Housing and Urban Development

24 CFR Part 60

RIN 2501-AA15

List of Subjects in 24 CFR Part 60

Human subjects, Research, Reporting and record-keeping requirements. Title 24 of the Code of Federal Regulations is amended by adding part 60 as set forth at the end of this document.

PART 60 PROTECTION OF HUMAN SUBJECTS

Sec.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Dated: January 16, 1991.

Jack Kemp,

Secretary, U.S. Department of Housing and Urban Development.

DEPARTMENT OF JUSTICE

28 CFR Part 46

RIN 1105-AA13

List of Subjects in 28 CFR Part 46

Human subjects, Research, Reporting and record-keeping requirements.

Title 28 of the Code of Federal Regulations is amended by adding part 46 as set forth at the end of this document.

PART 46—PROTECTION OF HUMAN SUBJECTS

Sec.

Authority: 5 U.S.C. 301; 28 U.S.C. 509–510; 42 U.S.C. 300v–1(b).

Dated: December 24, 1990.

Dick Thornburgh,

Attorney General.

DEPARTMENT OF DEFENSE

32 CFR Part 219

RIN 0790-AC80

List of Subjects in 32 CFR Part 219

Human subjects, Research, Reporting and record-keeping requirements.

Title 32 of the Code of Federal Regulations is amended by revising part 219 as set forth at the end of this document.

PART 219—PROTECTION OF HUMAN SUBJECTS

Sec.

219.101 To what does this policy apply?
219.102 Definitions.
219.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
219.104 [Reserved]
219.105 [Reserved]
219.106 [Reserved]
219.107 IRB Membership.
219.108 IRB functions and operations.
219.109 IRB review of research.
219.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
219.111 Criteria for IRB approval of research
219.112 Review by institution.
219.113 Suspension or termination of IRB approval of research.
219.114 Cooperative research.
219.115 IRB records.
219.116 General requirements for informed consent.
219.117 Documentation of informed consent.
219.118 Applications and proposals lacking definite plans for involvement of human subjects.
219.119 Research undertaken without the intention of involving human subjects.
219.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
219.121 [Reserved]
219.122 Use of Federal funds.
219.123 Early termination of research support: Evaluation of applications and proposals.
219.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).-

Dated: January 9, 1991.

Linda M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEPARTMENT OF EDUCATION

34 CFR Part 97

RIN 1875-AA07

List of Subjects in 34 CFR Part 97

Human subjects, Research, Reporting and record-keeping requirements.

Title 34 of the Code of Federal Regulations is amended by adding part 97 as set forth at the end of this document.

PART 97—PROTECTION OF HUMAN SUBJECTS

Sec.

97.101 To what does this policy apply?
97.102 Definitions.
97.103 Assuring compliance with this policy-research conducted or supported by any Federal Department or Agency.
97.104 [Reserved]
97.105 [Reserved]
97.106 [Reserved]
97.107 IRB Membership.
97.108 IRB functions and operations.
97.109 IRB review of research.
97.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
97.111 Criteria for IRB approval of research.
97.112 Review by institution.
97.113 Suspension or termination of IRB approval of research.
97.114 Cooperative research.
97.115 IRB records.
97.116 General requirements for informed consent.
97.117 Documentation of informed consent.
97.118 Applications and proposals lacking definite plans for involvement of human subjects.
97.119 Research undertaken without the intention of involving human subjects.
97.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
97.121 [Reserved]
97.122 Use of Federal funds.
97.123 Early termination of research support: Evaluation of applications and proposals.
97.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: June 6, 1991.

Lamar Alexander,

U.S. Secretary of Education.

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 16

RIN 2900-AE29

List of Subjects in 38 CFR Part 16

Human subjects, Research, Reporting and record-keeping requirements.

Title 38 of the Code of Federal Regulations is amended by adding part 16 as set forth at the end of this document

PART 16—PROTECTION OF HUMAN SUBJECTS

Sec.

16.101 To what does this policy apply?
16.102 Definitions.
16.103 Assuring compliance with this policy-research conducted or supported by any Federal Department or Agency.
16.104 [Reserved]
16.105 [Reserved]
16.106 [Reserved]
16.107 IRB Membership.
16.108 IRB functions and operations.
16.109 IRB review of research.
16.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
16.111 Criteria for IRB approval of research.
16.112 Review by institution.
16.113 Suspension or termination of IRB approval of research.
16.114 Cooperative research.
16.115 IRB records.
16.116 General requirements for informed consent.
16.117 Documentation of informed consent.
16.118 Applications and proposals lacking definite plans for involvement of human subjects.
16.119 Research undertaken without the intention of involving human subjects.
16.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency
16.121 [Reserved]
16.122 Use of Federal funds.
16.123 Early termination of research support: Evaluation of applications and proposals.
16.124 Conditions.

Authority: 5 U.S.C. 301; 38 U.S.C. 210(c)(1), 4131, 4134; 42 U.S.C. 300v-1(b).

Dated: February 19, 1991.

Edward J. Derwinski

Secretary of Veterans Affairs.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 26

RIN 2080-AA04

List of Subjects in 40 CFR Part 26

Human subjects, Research, Reporting and record-keeping requirements.

Title 40 of the Code of Federal Regulations is amended by adding part 26 as set forth at the end of this document.

PART 26—PROTECTION OF HUMAN SUBJECTS

Sec.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: January 28, 1991.

William K. Reilly,

Administrator.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

RIN 0991-AA71

List of Subjects in 45 CFR Part 46

Human subjects, Research, Reporting and record-keeping requirements.

Title 45 of the Code of Federal Regulations part 46 is amended, as follows:

1. An authority citation for subpart A is added to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 289, 42 U.S.C. 300v-1(b).

2. Subpart A is revised to read as set forth at the end of this document.

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Sec.

Dated: March 29, 1991.

Louis W. Sullivan,

Secretary of Health and Human Services.

NATIONAL SCIENCE FOUNDATION

45 CFR Part 690

RIN 3145-AA18

List of Subjects in 45 CFR Part 690

Human subjects, Research, Reporting and record-keeping requirements.

Title 45 of the Code of Federal Regulations is amended by adding part 690 as set forth at the end of this document.

PART 690—PROTECTION OF HUMAN SUBJECTS

Sec.

Dated: December 17, 1990.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Frederick M. Bernthal,

Acting Director.

DEPARTMENT OF TRANSPORTATION

49 CFR Part 11

RIN 2105-AB74

List of Subjects in 49 CFR Part 11

Human subjects, Research, Reporting and record-keeping requirements.

Title 49 of the Code of Federal Regulations is amended by adding part 11 as set forth at the need of this document.

PART 11—PROTECTION OF HUMAN SUBJECTS

Sec.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: February 4, 1991.

Samuel K. Skinner,

Secretary of Transportation.

[FR Doc. 91-14258 Filed 6-17-91; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Agency Forms Submitted to the Office of Management and Budget for Clearance

The following request has been submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). Expedited review by OMB has been requested as described below.

(Call PHS Reports Clearance Officer on 202-245-2100 for copies of submission)

Federal Policy for the Protection of Human Subjects—New—This submission is for approval of the information requirements associated with the common rule for the protection of human subjects of research conducted, supported or regulated by the following Federal departments and agencies: Department of Agriculture, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, Consumer Product Safety Commission, Agency for International Development, Department of Housing and Urban Development, Department of Justice, Department of Defense, Department of Education, Department of Veterans' Affairs, Environmental Protection Agency, Department of Transportation, Central Intelligence Agency, and Department of Health and Human Services.

Adoption of the common Federal policy by these departments and agencies will implement a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The Office of Science and Technology Policy established an Interagency Human Subjects Coordinating Committee under the Federal Coordinating Council for Science Engineering and Technology. This group prepared a proposed Model Federal Policy for the Protection of Human Subjects that was published as a proposed policy in 1986 and again as a proposed common rule on November 10, 1988. After revision of the proposed common rule in response to public comments, the final common rule is being published elsewhere in this issue of the **Federal Register.** The common rule is based on Department of Health and Human Services (DHHS) regulations (45 CFR part 46, subpart A), the basic HHS Policy for the Protection of Human Subjects.

Respondents: Individuals or households, State or local governments, businesses or other for-profit, Federal agencies or employees, non-profit institutions, small businesses or organizations.

The total number of respondents affected by these information requirements is estimated at 3,831. The total annual response burden for these requirements including all Federal departments and agencies subject to the common rule, is estimated at 187,408 hours divided as follows: 22,982 hours for recordkeeping requirements and 164,426 hours for reporting and disclosure requirements.

Additional Information:

DHHS has submitted this request for approval to OMB on behalf of all Departments and Agencies governed by this final rule. It is critical to receive OMB review and approval for the information requirements so that the common rule for the Protection of Human Subjects may be effective 60 days after publication. Federal Departments and Agencies have ongoing research programs to which the common rule will apply, and they are seeking the most expeditious time frame in which to begin protection of human subject policies and procedures. In addition, institutions supported or regulated by the involved Departments and Agencies have requested implementation of the final rule as soon as possible to lessen burden of compliance with numerous, sometimes inconsistent, procedures for the protection of human subjects required by the various Federal Departments and Agencies.

OMB has been requested to review and approve the information requirements in the common rule on an expedited basis no later than August 2, 1991. In keeping with the requirements for expedited review, we are publishing this announcement in the same issue as the proposed final rule. The information requirements are separately identified in the preamble to the rule, printed elsewhere in this issue. There are no separate forms or instructions for which approval is being sought.

OMB Desk Officer: Shannah Koss-McCallum.

Because of the time frame in which OMB has been asked to act on this request, any comments and recommendations for the proposed information collection should be provided directly to the OMB Desk Officer designated above by telephone at (202) 395-7316 or by express mail at the following address: Human Resources and Housing Branch, New Executive Office Building, room 3002, Washington, DC 20503.

Dated: May 31, 1991.

Sandra K. Mahkorn,

1Deputy Assistant Secretary for Public Health Policy.

[FR Doc. 91-14259 Filed 6-17-91; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50 and 56

[Docket No. 87N-0032]

RIN 0905-AC52

Protection of Human Subjects; Informed Consent; Standards for Institutional Review Boards for Clinical Investigations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on institutional review boards (IRB's) and on informed consent to conform them to the "Federal Policy for the Protection of Human Research Subjects" (Federal Policy) published elsewhere in this issue of the **Federal Register**. Existing FDA regulations governing the protection of human subjects share a common core with the Federal Policy and implement the fundamental principles embodied in that policy.

EFFECTIVE DATE: August 19, 1991.

FOR FURTHER INFORMATION CONTACT: Richard M. Klein, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is charged by statute with ensuring the protection of the rights, safety, and welfare of human subjects who participate in clinical investigations involving articles subject to section 505(i), 507(d), or 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i), 357(d), or 360j(g)), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.

In the **Federal Register** of January 27, 1981, FDA adopted regulations governing informed consent of human subjects (21 CFR part 50; 46 FR 8942) and regulations establishing standards for the composition, operation, and responsibilities of IRB's that review clinical investigations involving human subjects (21 CFR part 56; 46 FR 8958). At the same time, the Department of Health and Human Services (HHS) adopted regulations on the protection of human research subjects (45 CFR part 46; 46 FR 8366). The FDA and HHS regulations share a common framework.

In December 1981, the President's Commission for the study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the commission) issued its "First Biennial Report on the Adequacy and Uniformity of Federal Rules and Policies, and their Implementation, for the Protection of Human Subjects in Biomedical and Behavioral Research, Protecting Human Subjects." The commission recommended that all Federal departments and agencies adopt the HHS regulations (45 CFR part 46).

In May 1982, the President's Science Advisor, Office of Science and Technology Policy (OSTP), appointed an ad hoc Committee for the Protection of Human Research Subjects (the committee), under the auspices of the Federal Coordinating Council for Science, Engineering, and Technology (FCCSET), to respond to the recommendations of the commission. The committee, composed of representatives and ex officio members from departments and agencies that conduct, support, or regulate research involving human subjects, developed responses to the commission in consultation with OSTP and the Office of Management and Budget (OMB).

The committee agreed that uniformity of Federal regulations on human subject protection is desirable to eliminate unnecessary regulations and to promote increased understanding by institutions that conduct federally-supported or regulated research. The committee developed a model policy which OSTP later modified and, with the concurrence of all affected Federal departments and agencies, published as a proposal in the **Federal Register** of June 3, 1986 (51 FR 20204). More than 200 comments were submitted in response to the proposal. Published elsewhere in this issue of the **Federal Register** is the final rule on the Federal Policy.

FDA concurs in that final rule. In the **Federal Register** of November 10, 1988 (53 FR 45678), the agency proposed to amend its regulations in 21 CFR parts 50 and 56 to conform them to the Federal Policy to the extent permitted by the act. The agency is committed to being as consistent with the final Federal Policy as it can be, given the unique requirements of the act and the fact that FDA is a regulatory agency that rarely supports or conducts research under its regulations. However, as explained in the proposed rule, FDA must diverge from §§ _____.101(h) and _____.116(d) of the Federal Policy.

FDA received 22 comments on the proposed rule from sponsors of regulated research, institutional review board members and staff, academic institutions, medical societies, and lawyers. Several comments were prepared by organizations, each representing a consortia of institutions that had been polled concerning the proposed rule.

A. General Comments

1. The majority of comments supported the agency's efforts to conform to the Federal Policy.

2. The majority of comments received concerned the proposal to amend § 56.108(b) to require that IRB's follow written guidelines for ensuring the reporting of scientific misconduct and of unanticipated problems to the IRB, institutional officials, and FDA. Two comments noted that this provision would make the IRB the institutional body that investigates alleged fraud severely damaging the IRB/investigator relationship and possibly diminishing the effectiveness of the IRB in protecting human subjects. Several comments noted that the proposed additional reporting requirements would duplicate investigator and sponsor reporting requirements and would be difficult for the IRB to enforce. One comment said that this section may adversely affect the IRB/institution relationship and asked how FDA intended to ensure that reporting occurred. One comment interpreted the provision as applicable to animal studies and wondered whether IRB's would be responsible for contacting sponsors. One comment expressed concern that the workload of the IRB would increase and adversely affect the recruitment of new members. One comment sought to exclude Adverse Drug Reaction reports. One comment argued that the reporting requirement was unauthorized by law.

Two comments from sponsors requested that sponsor notification be added under proposed § 56.108(b), noting that an investigator engaged in misconduct is unlikely to report that misconduct to the IRB, and that the sponsor is the entity that frequently detects misconduct through its extensive monitoring practices. In addition, these comments requested clarification of the office in FDA to which scientific misconduct should be reported. Several comments requested that FDA define or clarify "scientific misconduct" and "unanticipated problems."

Since the proposed model policy was published, the Public Health Service published a final rule concerning fraud and misconduct in science (54 FR 32446,

August 8, 1989). Because that rule directs institutions to establish provisions for the investigation of alleged scientific fraud and misconduct, the mention of "scientific misconduct" has been deleted, as unnecessary, from the model policy. Because FDA only proposed to require that IRB's report scientific misconduct to be consistent with the model policy, it has deleted this requirement from its final rule. This action should allay many of the concerns expressed in the comments.

Moreover, FDA believes that the comments misconstrued the intent of § 56.108(b). This section requires simply that an IRB have procedures by which it checks to ensure in reviewing each study presented, that provision has been made in the study to notify the IRB, appropriate institutional officials, and FDA in the specified circumstances. Section 56.108(b) does not require that the IRB itself provide the notification to either the institution or to FDA, unless such reporting would not otherwise occur. Although FDA's regulations include reporting requirements for certain types of investigational articles (see, e.g., 21 CFR parts 312 (investigational drugs) and 812 (investigational devices)), there are no such provisions for other articles that may be the subject of an investigation (e.g. food additives). Because all regulated research to be conducted at an institution will come before the IRB, FDA finds that the IRB is the appropriate entity to charge with the responsibility for ensuring that reporting of the specified problems to the IRB, the institution, and the agency will occur.

3. One comment urged FDA to move toward the adoption of an assurance system as established for the other agencies within HHS to guarantee compliance with regulations for the protection of human subjects.

FDA continues to believe that it would be inappropriate for it to adopt this mechanism. As stated in the final rule in the **Federal Register** of January 27, 1981 (46 FR 8959, comment 2), the benefits of assurance from IRB's that are subject to FDA jurisdiction, but not otherwise to HHS jurisdiction, do not justify the increased administrative burdens that would result from an assurance system. FDA relies on its Bioresearch Monitoring Program, along with its educational efforts, to assure compliance with these regulations.

4. One comment expressed concern over FDA's proposed divergences from sections 101(h) and 116(d) of the Federal Policy. The comment contended that it is sometimes impossible to obtain informed consent, as defined by FDA's regulations, in foreign clinical trials.

As stated in the proposed rule (53 FR 45679), FDA does not have the authority to accept the procedures followed in a foreign country in lieu of informed consent as required by the act for studies that are conducted under a research permit that it grants. The comment did not provide any information that would compel a different conclusion.

B. Comments on Definitions

5. One comment suggested that the word "discomfort" used in proposed §§ 50.3(i) and 56.102(i) is difficult to define and is subjective.

FDA believes that the meaning of "discomfort" is sufficiently clear. FDA interprets this term to have its ordinary meaning; that is, to mean the extent to which a subject may be made uncomfortable by the article that is the subject of the research.

6. One comment asserted that proposed § 56.102(m), the definition of "IRB approval," suggests an intent to change the procedural requirements of IRB approval.

FDA proposed to add this definition to make the regulations conform to the Federal Policy and to clarify the meaning of the phrase "IRB approval" under this rule. The addition of this definition is not intended to effect a substantive change in part 56. In the preamble to its August 8, 1978 proposal of the IRB regulation (43 FR 35186 at 35197), FDA presented a thorough discussion of its authority to require IRB review.

7. One comment stated that the reference to "other institutional and Federal requirements" in proposed § 56.102(m) goes beyond FDA's ability to determine other institutional requirements and may be counterproductive where there is conflict between the institutional requirements and FDA or HHS requirements. The suggestion is made to delete "and other institutional * * * requirements."

This definition is intended to make clear that IRB approval is to be based on a determination that the proposed research is acceptable under any applicable institutional requirements, applicable law, and standards of professional conduct and practice. If there are conflicts between the institutional requirements and Federal law, those conflicts obviously must be resolved in favor of the Federal law. However, institutional requirements often address matters not addressed by Federal law. Therefore, FDA finds it appropriate to mention both institutional and Federal requirements in this definition.

8. One comment suggested substituting "clinical investigation" for the word "research" in § 56.102(m).

FDA rejects the suggestion. FDA has defined "clinical investigation" in § 56.102(c) to be synonymous with "research" (46 FR 8976). Because FDA desires to conform to the Federal Policy and in the absence of a compelling argument to diverge from it, FDA is using the word used in the Federal Policy.

9. Several comments suggested deleting "at an institution" from § 56.102(m), contending that this phrase may confuse the original intent of the meaning of IRB approval. Another comment noted that much research today is conducted outside the institutional setting.

FDA rejects the comments. In 1981, when FDA adopted the IRB regulations, FDA intentionally defined "institution" broadly to include "any public or private entity or agency" (§ 56.102(f); 46 FR 8963, comment 27). Thus, § 56.102(m) is consistent with the original intent of the IRB regulations.

10. One comment suggested revising § 56.102(m) to read "IRB approval means * * * that the research has been reviewed for undue risk to the subject and may be conducted * * *."

FDA rejects the suggestion. The suggested change does not adequately describe the role of the IRB. The IRB's review of studies and informed consent documents includes numerous considerations in addition to whether the study presents undue risks to the human subjects involved.

C. Comments on Exemptions From IRB Requirements

11. One comment requested that no exemptions from IRB requirements be granted for those populations already identified as vulnerable.

FDA did not propose that studies involving vulnerable populations be exempt from IRB review. The only exemptions from the IRB review requirements were established in the 1981 final rule (46 FR 8942; 21 CFR 56.104). The use of an investigational article is exempt from IRB review if the investigation started before July 27, 1981, before the requirement of IRB review was in effect, or if it involves an emergency use of the test article, in which case there is not time for IRB review before the article is used. The agency found that in these circumstances, the considerations that support granting an exemption outweigh those that would support denying it (46 FR 8965, comment 48). The comment did not provide any basis for reconsidering

or revising this judgment. The agency points out that the latter consideration (emergency use), which is the only basis on which a new study would be exempt, applies only to particular uses of an article and would not provide the basis for an exemption for the use of an article in a particular population. Therefore, FDA finds that this comment provides no basis for modifying its regulations.

12. One comment suggested that FDA completely exempt "minimal risk" studies from IRB review.

FDA rejects the comment. The determination of minimal risk can be made only by members of the IRB, not the investigator or the sponsor. The burden of an expedited review of a protocol to determine if it presents minimal risk is not so great as to justify the requested exemption.

D. Comments on IRB Membership

13. Three comments suggested that FDA define in § 56.107 the specific members to be included on an IRB. Several comments suggested that FDA define, in new § 56.107(c), "non-scientific" and "scientific." Two comments suggested that the IRB include "one member who has an understanding of the medical risks involved." Another comment suggested that § 56.107(c) be clarified to include a statement requiring that at least one member of the IRB have an understanding of the scientific method.

FDA rejects these comments. FDA has chosen not to prescribe professional membership requirements for IRB members. The regulations allow for flexibility in the makeup of the IRB (see 43 FR 8966, comment 55). They require, however, that there be at least one member whose concerns are in nonscience areas and one member who has the professional competency to review the proposed research, such as a physician. FDA interprets "competency" in this context to include the ability to understand the scientific method. The agency believes that the membership requirements that it has adopted are adequate to ensure that an IRB will be able to fully consider the issues presented by a study.

14. One comment suggested that the proposed change in § 56.107(a), allowing IRB's that regularly review studies that involve vulnerable categories of subjects to consider including as a member an individual knowledgeable about, and experienced in, working with vulnerable populations, will afford less human subject protection than the current regulation.

The current regulation states that an IRB that regularly reviews research involving vulnerable populations should include as members individuals who are primarily concerned with the welfare of vulnerable subjects. Revised § 56.107(a) lists categories of subjects who are considered vulnerable and requires that the institution, or other authority, consider including individuals knowledgeable and experienced in working with these types of subjects as voting members on the IRB. This revision is not intended to lessen in any way the protections for vulnerable populations under FDA's regulations. As explained in the proposal (53 FR 45679), FDA is making this change only to conform to the language of the Federal Policy.

FDA on its own initiative is adding parenthesis to the word "reviewers" in § 56.110(b)(1) to permit a continuance of existing IRB review procedures.

E. Comments on IRB Functions and Operations

15. Several comments sought clarification of new § 56.108(b)(1) with regard to the definition and interpretation of "any unanticipated problems involving risks to human subjects and others" and the level of risk to be reported.

FDA interprets this phrase to mean an unexpected adverse experience that is not listed in the labeling for the test article. Such experience includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling but that differs from the event because of greater specificity or severity. The word "others" has previously been defined as persons who are participating in clinical trials under the same or similar protocols or who may be affected by products or procedures developed in those trials (see 53 FR 45661, 45665; November 10, 1988).

F. Comments on Expedited Review Procedures

16. One comment read the parenthetical change in § 56.110(b), "of one year or less," as affecting a change from the current regulations.

FDA disagrees with the comment. Under current regulations, the IRB may approve a study that will continue beyond 1 year, such as a longitudinal followup study. The IRB is obligated, however, under § 56.109(e) (21 CFR 56.109(e)), to conduct continuing review of the research at intervals appropriate to the degree of risk that it presents but not less than once a year.

17. One comment stated that expedited review procedures should never be used in research that involves vulnerable populations.

FDA disagrees with the comment. Expedited review procedures may only be used to review research that involve minimal risk as defined in § 56.102(i) or to review minor changes in previously approved research (§ 56.110(b)). The determination that such conditions apply must be made by the chairperson of the IRB, or by one or more experienced members of the IRB designated by the chairperson. Thus, research involving vulnerable populations will not be subject to expedited review unless a member of the IRB has affirmatively determined that the subjects will not be exposed to any greater risk of harm than they encounter in daily life or during routine physical or psychological examination or tests, or that a change in research that has been reviewed by the whole IRB is minor. Obviously, in making the determinations, the IRB member must consider the nature of the subject population. Moreover, if expedited review is undertaken, the reviewer may exercise all the authority of the IRB, including the authority under § 56.111(a)(3) to ensure that any specific problems of vulnerable populations have been addressed. Thus, FDA believes that vulnerable populations will not be involved in research that has been subject to expedited review procedures without full consideration whether such research should be subject to expedited review at all and, if so, on their interests. Therefore, FDA does not agree with the comment.

G. Comments on Criteria for IRB Approval of Research

18. One comment suggested deleting "* * * economically or educationally disadvantaged persons * * *" from new § 56.111(a)(3), stating that it would be impossible for the IRB or the clinical investigator to make that determination.

FDA disagrees with the comment. As stated in § 56.111(b), FDA expects the IRB to make sure that adequate protections are included in those clinical investigations in which vulnerable subjects will be participating. There is no requirement for the IRB to make a determination that individual subjects are disadvantaged. However, the IRB is required to determine whether it is likely that vulnerable individuals will be involved in the study, and, if so, whether adequate safeguards have been included to protect the study subjects or whether additional safeguards are necessary.

II. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or

cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Economic and Regulatory Assessments

FDA has examined the economic consequences of the final amendments to its regulations pertaining to IRB's and to informed consent in accordance with the criteria in section 1(b) of Executive Order 12291 and found that these amendments would not be a major rule under the Executive Order. The agency also has considered the effect that the final rule would have on small entities including small businesses in accordance with the Regulatory Flexibility Act (Pub. L. 96-354). The agency certifies that there will not be a significant economic impact on a substantial number of small entities. FDA explained the basis for these conclusions in the proposal (53 FR 45681). The agency did not receive any comments that suggest contrary conclusions. This final rule contains information collections subject to the Paperwork Reduction Act of 1980. These information collections have been approved under OMB control number 0910-0130.

List of Subjects in

21 CFR Part 50

Prisoners, Reporting and recordkeeping requirements, Research, Safety.

21 CFR Part 56

Reporting and Recordkeeping requirements, Research, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, 21 CFR parts 50 and 56 are amended as follows:

PART 50—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 21 CFR part 50 continues to read as follows:

Authority: Secs. 201, 406, 406, 409, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 706, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 346, 346a, 349, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 376, 381); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

2. Section 50.3 is amended by revising paragraph (l) to read as follows:

§ 50.3 Definitions.

* * * * *

(l) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

* * * * *

PART 56—INSTITUTIONAL REVIEW BOARDS

3. The authority citation for 21 CFR part 56 continues to read as follows:

Authority: Secs. 201, 406, 408, 409, 501, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 706, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 346, 346a, 349, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 376, 381); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

4. Section 56.102 is amended by revising paragraph (i) and by adding new paragraph (m) to read as follows:

§ 56.102 Definitions.

* * * * *

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

* * * * *

(m) *IRB approval* means the determination of the IRB that the clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

5. Section 56.104 is amended by adding new paragraph (d) to read as follows:

§ 56.104 Exemptions from IRB requirement.

* * * * *

(d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6. Section 56.107 is amended by revising paragraphs (a), (b), and (c) to read as follows:

§ 56.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about the experienced in working with those subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the instituton's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.

* * * * *

7. Section 56.108 is amended by revising paragraph (a), by removing paragraph (c), by redesignating paragraph (b) as paragraph (c), by adding a new paragraph (b), and by adding a parenthetical statement to the end of the section to read as follows:

§ 56.108 IRB functions and operations.

(a) Follow written procedures: (1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (2) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review; (3) for ensuring prompt reporting to the IRB of changes in

research activity; and (4) for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of: (1) Any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.

* * * * *

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0130)

8. Section 56.110 is amended by revising paragraph (b) to read as follows:

§ 56.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

* * * * *

(b) An IRB may use the expedited review procedure to review either or both of the following: (1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk, (2) minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the IRB chairperson from among the members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited review procedure set forth in § 56.108(c).

* * * * *

9. Section 56.111 is amended by revising paragraphs (a)(3) and (b) to read as follows:

§ 56.111 Criteria for IRB approval of research.

(a) * * *

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

* * * * *

(b) When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects.

10. Section 56.115 is amended by revising paragraph (a)(6) and by adding a parenthetical statement to the end of the section to read as follows:

§ 56.115 IRB records.

(a) * * *

(6) Written procedures for the IRB as required by § 56.108 (a) and (b).

* * * * *

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0130)

Dated: March 29, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF EDUCATION

34 CFR Parts 350 and 356

Protection Of Human Subjects—Disability and Rehabilitation Research: General Provisions, Disability and Rehabilitation Research: Research Fellowships

AGENCY: Department of Education.

ACTION: Interim final regulations with an opportunity to comment.

SUMMARY: The Secretary amends program regulations for the National Institute on Disability and Rehabilitation Research to add certain protections for handicapped children and mentally disabled persons who are the subjects of research conducted or sponsored by those programs. Specifically, the program regulations would require that when an institutional review board (IRB) reviews research involving these research subjects, the IRB must include at least one person who is primarily concerned with the welfare of the research subjects. The regulations are necessary as the result of the Department of Education's (Department) withdrawal of a departure from the common regulations for the protection of human research subjects.

DATES: Comments must be received on or before August 2, 1991. These regulations take effect either August 19, 1991, or later if the Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person. A document announcing the effective date will be published in the Federal Register.

ADDRESSES: All comments concerning these interim final regulations should be addressed to Mr. Edward Glassman; Office of Planning, Budget and Evaluation; U.S. Department of Education, Federal Building #6, room 3127, 400 Maryland Avenue SW., Washington, DC 20202-4132.

FOR FURTHER INFORMATION CONTACT: Edward B. Glassman, Telephone: (202) 401-3132. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1-800-877-8339 (In the Washington DC area, 202 708-9300) between 8 a.m. and 7 p.m. Eastern Time.

SUPPLEMENTARY INFORMATION: The Office of Science and Technology Policy, Executive Office of the President (OSTP), published a "Proposed Model Policy for the Protection of Human Subjects" in the Federal Register on June 3, 1986 (51 FR 20204). OSTP adopted a final policy for the protection of human research subjects on November 10, 1988 (53 FR 45660). The Final Policy adopted by OSTP was included in proposed common regulations published in the Federal Register on November 10, 1988 (53 CFR 45661) by sixteen departments and agencies in the Executive Branch of the Federal Government, including the Department of Education. The final common regulations are published in another section of this Federal Register part.

The notice of proposed rulemaking (NPRM) for the common regulations specifically asked for comments addressing what effect promulgation of the Model Policy would have on each of the agencies involved in the proposed rulemaking. The Secretary proposed a departure from the common regulations that would require representation on an Institutional Review Board (IRB) of at least one person primarily concerned with the welfare of the research subjects whenever the research involves handicapped children or mentally disabled persons. As discussed below,

the Secretary has decided to withdraw this across-the-board departure in favor of program-specific regulations under those programs of the Department that are likely to support covered research that involves these research subjects.

Composition of the IRB

Comment

The Department proposed a departure to § ____.107(a) of the common regulations that would have required that, for all programs of the Department, "when an IRB reviews research that deals with handicapped children or mentally disabled persons, the IRB shall include at least one person primarily concerned with the welfare of the research subjects." The remainder of the departure reiterated the common rule's provision, which required institutions to consider representation on the IRB of persons who are knowledgeable about and experienced in working with certain vulnerable subjects if the IRB regularly reviews research involving those vulnerable subjects. Twenty-one institutions focused on this proposed departure in their comments. The majority of these comments were opposed to the proposed departure.

Some commenters, while supporting the proposed general language in § ____.107, stated their belief that the departure was not necessary because the policy in § ____.107 already addresses representation of the special concerns of vulnerable subjects on the IRB. Thus, the rights of handicapped children and mentally disabled persons should be represented on any IRB that regularly reviews proposals involving those individuals and there is nothing to be gained by emphasizing these two categories of subjects. Such an emphasis was seen as a precedent with the potential for discrimination against other categories of vulnerable subjects. When special expertise is required, IRBs already have the option, and, they believed, the obligation to seek informed consultants. However, one commenter stated "if in future staffing of our IRB, someone with expertise in this area is available and willing to serve, we would be happy to encourage such participation."

One commenter suggested that only when an IRB regularly reviews research that deals with handicapped children or mentally disabled persons should the IRB include at least one person primarily concerned with the welfare of the research subjects. Otherwise, consultation should take place when appropriate. Another suggestion was that handicapped children be added to the list of examples of vulnerable subjects for which an IRB that regularly reviews research might want to consider inclusion of one or more members who are knowledgeable about and experienced in working with these subjects.

Some commenters objected to the lack of consistency among Federal agencies and cited the Department of Education's proposed departure as inconsistent with the purpose of the common rule. One commenter indicated that the departure would not pose any problem.

Response

The language of the proposed departure was rooted in the Secretary's concern that the welfare of research subjects who are handicapped children or mentally disabled persons be adequately protected because of the diminished capacity of such persons to protect their own interests and their corresponding greater potential for harm. It should be noted that, while the common rule does, in general, protect the interests of vulnerable populations, it does not specifically command representation of their interests in all cases. For example, the common rule only requires that when an IRB regularly reviews research involving vulnerable subjects, consideration should be given to including on the IRB a researcher experienced in working with such subjects. Thus, the Department believes it is appropriate to offer special protection for handicapped children and mentally disabled persons, and the protection proposed in the departure would have satisfied that need.

The comments also appear to misunderstand the intent of the Department's proposed departure. Some commenters believed that the departure would require that an IRB include a permanent member to represent the special populations covered by the departure. Others appeared to believe that the departure would apply to all research of the institution that involved the special populations covered by the departure. The proposed departure would have produced neither of these results. Instead, the proposed departure would have required the addition of one member on an *ad hoc* basis only when the research is sponsored or funded by the Department of Education and purposefully requires the inclusion of handicapped children or mentally disabled persons.

As explained above, the Secretary believes that there is a special need to protect handicapped children and mentally disabled persons. However, given the broad policy objective of providing consistent treatment through common regulations, the Secretary has decided that the IRB special representation requirements contained in the proposed departure are not necessary for most of the programs of the Department, because most programs of the Department do not support research likely to involve those persons. Thus, the Secretary has decided to withdraw the departure. However, the Secretary believes that the concerns addressed by the proposed departure have a particular urgency in those programs of the Department that support a significant amount of research involving handicapped children and mentally disabled persons. Therefore, the Secretary is amending the regulations for the programs of the National Institute on Disability and Rehabilitation Research (34 CFR parts 350 and 356) to ensure that the protections that would have been afforded under the departure are implemented in those specific programs.

Although the Secretary has decided to publish this regulation in final form, due to the strong public interest created by the proposed departure, and because a number of commenters appeared to misunderstand the effect of the proposed rule, the Secretary has also decided to offer the public an additional opportunity to comment on the final rule. The address to which commenters should send their comments and the date by which those comments must be received is stated at the beginning of this preamble.

Changes

In the notice of proposed rulemaking, the proposed departure was stated as follows: "When an IRB reviews research that deals with handicapped children or mentally disabled persons, the IRB must include at least one person primarily concerned with the welfare of the research subjects." The Secretary has decided to change this language in the program-specific regulations adopted in this document to make clear that the regulation specifically protects handicapped children and mentally disabled persons when those persons are purposefully included in a research protocol, rather than incidentally. Therefore, the language has been changed to state: "When an IRB reviews research that purposefully requires inclusion of handicapped children or mentally disabled persons in the research sample, the IRB must include at least one person primarily concerned with the welfare of the research subjects."