federal register

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

Editorial Note: This reprint incorporates a correction document published in the **Federal Register** of June 28, 1991.

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.

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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

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22 CFR Part 225

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24 CFR Part 60

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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. The 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 an 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,

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 or 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 or agency heads, and which are designed to study, evaluate, or otherwise examine: