

#1792



Name: Rudolph, Kim

U.S. Department of Education
Office of the Deputy Secretary/Budget Service - Control Document

Assigned to: ODS/BS

Control #: BS01-01394
ODS/BS Doc #: 6930

Action: REVIEW/COMMENT
Signature:

Doc. Type: OMB
Due Date: 07/09/2001

Writer: Rudolph, Kim
Title:
Organization: RIMG
Salutation:

Subject: REQUEST FOR OMB REVIEW: APPLICATION FOR FEDERAL EDUCATION ASSISTANCE (AFEA)

Notes:

----- Assignment Tracking Section -----

ASSIGNED	COMMENT	DATE	DUE	COMPLETED
CICHOWSK	REVIEW/COMMENT	06/28/2001	07/09/2001	7-5-01
BRISOE	See comment CAC			

RIMG RECEIPT CONTROL

PLEASE SIGN AND DATE AS INDICATED UPON RECEIPT.

ANALYST:	Kathy Axt 703-426-9692	<input type="checkbox"/>	<input type="checkbox"/>
	Shella Carey 708-6287	<input type="checkbox"/>	<input type="checkbox"/>
	Jackie Montague 708-5359	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Joe Schubart 708-9266	<input type="checkbox"/>	<input type="checkbox"/>

OMB NUMBER

1875-0106

TITLE

Application for Federal Education Assistance (AFEA)

PROGRAM OFFICE

- OGC
- OESE
- OSERS
- OVAE
- OPE
- OERI
- OIIA
- OUS**
- OM
- OBEMLA
- OTHER

FROM: RIMG CONTROL DESK

FOR BUDGET AND PLANNING USE ONLY – HIGHLIGHT THE NAME OF THE REVIEWER

Signature:				Date:			
Alan Ginsburg, PES	401-3132	Angel Clarke	""	Valerie Sciarra	401-0333	James Butler	401-0311
Sandra Richardson	""	Sarah Abernathy	401-3600	Lee Terry	401-3037	John Chapman	401-0309
Axalea Saunders	""	Sandra Furey	401-4614			David Cleary	205-9963
Genise Cooke	""	David Goodwin	401-0263	Linda Chiamonte, ABAD	401-1288	Larry Cohen	401-0310
Jennifer Ballen	401-0618	Elizabeth Eisner	401-1857	Faith Turner	401-7919	James Houser	401-0307
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Julie Pederson	401-2871	Andrew Lauand	401-3518	Patricia James	401-7882	Betty McRoy	"
Nancy Rhett	401-1679	James Maxwell	401-3571	Debra Scites	260-5289	Eleanor Briscoe	401-1201
Lenore Garcia	401-3036	Daniel Morrissey	401-3619	Winifred Shapiro (PT)	401-1751	Mark Traversa	401-0122
Shirley Sands	401-0430	Ann Nawaz	401-5344	Susan Taylor	401-1392	Phillip Juengst	260-1760
Samuel McKee	""	Stacy Kotzin	401-5938	Elizabeth Witherspoon	401-0229	Navneeta Chandra	401-7543
Betty Ward	""	Audrey Pendleton**	401-3630	William Graham, CEA	401-0975	Carol Cichowski, SERRAD	401-3939
Christopher Winkler*	""	Steven Zwilling	401-1678	Janice Matthews	401-0290	Kelly Munger	401-7320
		Thomas Skelly, Budget	401-1700	William Carrington	401-1848	Krystal Southall (PT)	401-3940
Yvonne Briscoe	""	Marie Wade	""	Mike Carpenter	401-0336	Laurie Collins	401-3981
Joanne Bogart	401-0276			Kimberly Carroll	401-3870	Gregory Frane	401-3948
Melissa Chabran	401-1265	Bill Cordes	""	John Kane	401-1859	Wava Gregory	401-1345
Martha Chavez	401-8368	James Hazzard	""	Larry Kean	401-0330	Ellen Weiss	401-3947
Barbara Coates	401-1232	Jan Solomon	""	Shannon Mahan	401-0328	Mark Snyderman	401-1949
Katherine Doherty	401-0264	Susan Weiner, BPCS	401-1845	Robert Mercer	401-9031	Judith Anderson	401-3944
Daphne Hardcastle	401-7949	Sandra Johnson	401-0320	Rachael Bauer	401-2931		
Tracy Rimdzius	401-1259	Marilyn Bechtold	401-1844	Kirk Siegwarth	401-0338		
Mary Rollefson	401-0274			Robin Pugh	401-2152		
Jeffrey Rodamar	204-5046	Ray Hamilton	401-1763	Mark Santucci	260-8975		
Colette Roney	401-0886	Martha Jacobs	401-0098				
Susan Sanchez	401-0886	Nancy Martin	401-0292	Alan Baldinger	401-0976		
Elois Scott **	401-0274	Kathleen McAuliffe	401-1847	Michael Ward	401-5949		
Stephanie Stulich	401-0091			Daniel Simpson	401-0122		
Susan Thompson-Hoffman	401-0091	Trina Lawson, BECS	401-1391	Thomas Corwin, DESVA	401-0318		
Lisa Towne	205-5798	Kathleen Guy	401-2227	Laurette Crum	205-9149		
Joanne Wiggins	401-2266			Ian Soper	401-0907		
Ricky Takai**, PAVED	401-3630	Ann Kibler	401-3946	Chelsea Hart	401-0317		
Daniel Goldenberg	401-3562			Barbara Broadnax	401-0318		

PLEASE REVIEW AND RETURN COMMENTS TO: RIMG, ROB3, RM. 4050 ATTENTION: KIM RUDOLPH

NO LATER THAN

July 11, 2001

Marie Wade 6/27/01

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street, NW, Washington, DC 20503.

1. Agency/Subagency originating request: U.S. Department of Education Office of the Chief Financial Officer Grants Policy and Oversight Staff	2. OMB control number: a. 1875-0106 b. { } NONE: _____ - NEW
3. Type of information collection (check one): a. [] New collection b. [] Revision of a currently approved collection c. [] Extension of a currently approved collection d. [X] Reinstatement, with change, of a previously approved collection for which approval has expired e. [] Reinstatement, without change, of a previously approved collection for which approval has expired f. [] Existing collection in use without an OMB control number	4. Type of review requested (check one): a. [X] Regular (if streamlined also check here <input type="checkbox"/> b. [] Emergency - Approval requested by: ___/___/___ c. [] Delegated 5. Small entities: Will this information collection have a significant economic impact on a substantial number of small entities? [] Yes [X] No 6. Requested expiration date: a. [X] Three years from approval date b. [] Other - Specify: ___/___/___
7. Title (10-15 words maximum): Application for Federal Education Assistance (AFEA)	
8. Agency form number(s) (if applicable): Not Applicable	
9. Keywords: Federal Education Financial Assistance	
10. Abstract: Need to collect information necessary for the processing of various Department of Education grant program's application packets from State and Local educational agencies, institutions of higher education. Information is used by program offices to determine eligibility and facilitate in the disbursement of program funds.	
11. Affected Public (mark primary with "P" and all others that apply with "X") a. [X] Individuals or households d. [] Farms b. [] Businesses or other for-profit e. [] Federal Government c. [X] Not-for-profit institutions f. [P] State, local or Tribal Gov't, SEAs or LEAs	12. Obligation to respond (Mark primary with "P" and all others that apply with "X"): a. [] Voluntary b. [P] Required to obtain or retain benefits c. [] Mandatory
13. Annual reporting and recordkeeping hour burden: a. Number of respondents 17,000 b. Total annual responses 17,000 Percentage of these responses Collected electronically 4 % c. Total annual hours requested 4,250 d. Current OMB inventory 3,888 e. Difference (+/-) + 362 f. Explanation of difference 1. Program change 362 2. Adjustment	14. Annual reporting and recordkeeping cost burden (in thousands of dollars): a. Total annualized capital/startup costs 0 b. Total annual costs (O&M) 0 c. Total annualized cost requested 0 d. Current OMB inventory 0 e. Difference (+/-) 0 f. Explanation of difference 1. Program change 0 2. Adjustment 0
15. Purpose of information collection (mark primary with "P" and all others that apply with "X"): a. [P] Application for benefits e. [] Program planning or management b. [X] Program evaluation f. [] Research c. [] General purpose statistics g. [] Regulatory or compliance d. [] Audit	16. Frequency of recordkeeping or reporting (check all that apply): a. [] Recordkeeping b. [] Third party disclosure c. [X] Reporting 1. [] On occasion 2. [] Weekly 3. [] Monthly 4. [] Quarterly 5. [] Semi-annually 6. [X] Annually 7. [] Biennially 8. [] Other (describe) _____
17. Statistical methods: Does this information collection employ statistical methods? [] Yes [X] No	18. Agency contact (person who can best answer questions regarding the content of this submission): Name: Julie Laurel Phone No.: 202-205-8796 Fax No.: 202-205-0667 Email: Julie_Laurel@ed.gov
19. Regulatory information (information provided in this block will be used to improve the processing of the information collection): a. Does this collection contain a proposed regulation? [] Yes [X] No If yes, check item that applies: [] NPRM [] Final [] Other _____ b. List all sections that apply to this collection that have paperwork burden:	

20. Certification for Paperwork Reduction Act Submissions

On behalf of this federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8 (b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of topics, regarding the proposed collection of information, that the certification covers:

- (a) It is necessary for the proper performance of agency functions;
- (b) It avoids unnecessary duplication;
- (c) It reduces burden on small entities;
- (d) It uses plain, coherent, and unambiguous terminology that is understandable to respondents;
- (e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;
- (f) It indicates the retention periods for recordkeeping requirements;
- (g) It informs respondents of the information called for under 5 CFR 320.8 (b)(3):
 - (i.) Why the information is being collected;
 - (ii.) Use of information;
 - (iii.) Burden estimate;
 - (iv.) Nature of response (voluntary, required for a benefit, or mandatory);
 - (v.) Need to display currently valid OMB control number;
- (h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of information to be collected (see note in Item 19 of the instructions);
- (i) It uses effective and efficient statistical survey methodology; and
- (j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain The reason in Item 18 of the Supporting Statement

Signature of Senior Official or designee 	Date 06-13-01
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For Department of Education Internal Use	
I certify that the information collection being submitted to the Senior Official, or designee, encompassed by this request complies with 5 CFR 1320.9, as summarized above. <i>(Assistant Secretary signature required for emergency reviews.)</i>	
Signature of Assistant Secretary or designee	Date

Table of Contents

- I. Request for OMB Review: SF 83-1
- II. Supporting Statement for Application for Federal Education Assistance
- III. Additions and Deletions

Appendices

Appendix A - Application for Federal Education Assistance

Appendix B - OMB Circular A-102

Appendix C - CFR 34 Part 74--Administration of Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations

Appendix E - 34 CFR Part 97--Protection of Human Subjects, Final Rule

I. Request for OMB Review: SF 83-1

II. Supporting Statement

**Supporting Statement for:
Application for Federal Education Assistance**

A. Justification

- 1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitates the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

The Application for Federal Education Assistance (AFEA) is used for numerous Department of Education (ED) discretionary, formula, and fellowship grant programs. The AFEA is necessary in that it identifies applicants and provides important descriptive information which facilitates the grant-making process. The proposed information collection instrument is based on current legislation and regulations published to implement the legislation.

The statutory and regulatory requirements in determining Federal education grant assistance is found in the Office of Management Budget (OMB) Circular A-102, A-110, and A-21. In addition, the regulatory requirement for collecting information related to the "Protection of Human Subjects is in 34 CFR Part 97.

- 2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.**

The information is used by the Office of Postsecondary Education (OPE), Office of Elementary and Secondary Education (OESE), Office of Special Education and Rehabilitative Services (OSERS), Office of Vocational and Educational Assistance (OVAE), Office of Bilingual Education and Minority Language Affairs (OBEMLA), Office of Educational Research and Improvement (OERI), and the Office of the Chief Financial Officer (OCFO). The information collected on the AFEA is used to register and identify applicants for federal educational assistance, and to administer the distribution of the respective program funds, and to assign the PR/Award number. The information allows for monitoring federal funds in order to eliminate fraud, waste, and mismanagement by capturing and identifying applicant data. Furthermore, information collected on the AFEA such as identifiers (e.g., DUNS, project information, etc.) allows for the submission of any additional materials or data that may be required to process the application. If the information collection is not conducted, program funds could not be disbursed because of insufficient information necessary to verify applicant eligibility and other program requirements. *Note: The proposed AFEA is not a new collection, but rather a reinstatement (with changes) of a previously expired AFEA.*

- 3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or forms of information technology (e.g., permitting electronic submission of responses, and the basis for the decision of adopting this means of collection). Also describe any consideration of using information technology to reduce burden.**

The revised AFEA complements the Department's strategic plan element to increase the use of technology in its work processes. More importantly, the National Performance Review encourages Federal agencies to increase their use of technology to ease the burden on both the applicant and the Federal government. With these two goals in mind, the Department has moved to both an automated (GAPS) and electronic (e-grants) method of collecting and processing data to determine eligibility for discretionary grants. ED's e-application is a Pilot on-line application system that allows applicants to apply on-line to a specially selected group of grants.

- 4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in item 2.**

The SF-424 is the only potential source of partial duplication of information. However, no program will use both the SF 424 and the AFEA. The AFEA is used by all ED's discretionary grant program offices, therefore, no duplication of information will exist from other sources. More importantly, the AFEA contains elements which are unique to ED's grant-making process and not contained on the SF-424. For example, in addition to using the Taxpayer Identification Number (TIN) for the purpose of conducting business with the Department of Treasury, ED uses a unique nine-digit number (DUNS) to identify grant applicants. While not all applicants have TINs, all applicants for discretionary, formula, and fellowship grants are given a DUNS.

- 5. If the collection of information impacts small business or other small entities (item 5 of OMB Form SF 83-1), describe any methods used to minimize burden.**

The collection of information does not involve small businesses.

- 6. Describe the consequences to Federal program or policy activities if the collection is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

The administration, determination and distribution of program funds could not be accomplished if the information was collected less frequently. The frequency of the application is mandated by the respective legislative and program regulations.

In an effort to reduce redundancy, the ED has streamlined the separate continuation process for all of the grant programs. An example of streamlining the AFEA to better serve the needs of the grantees is to eliminate data elements that are not relevant in the grant application process or to eliminate data elements that are contained in other databases. The ED has identified several data elements on the current AFEA that will be eliminated.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- requiring respondents to report information to the agency more often than quarterly;
- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

No collection conduct is inconsistent with any of the above items.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instruction and record keeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

While the Department did not directly consult with persons outside the agency to obtain their views on the proposed instrument collection tool, the OCFO did consult with the representatives from OPE, OESE, OSERS, OVAE, OBEMLA, and OERI in both the headquarters and the regional offices. The comments and recommendations received by the various program offices, represented, for the most part, concerns raised by the community regarding the complexity of the previous instrument collection tool.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts are provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulations, or agency policy.

The information provided is used in line with the Privacy Act Notice in the Federal Register on the ED's Financial Management Information System 18-11-0027. The information is disclosed under the circumstances necessary to administer the programs for which the information is being collected.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

No questions of a sensitive nature are included on the AFEA.

12. Provide estimates of the hour burden of the collection of information. The statement should:

-Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.

**Table 1
Respondent's Hour Burden**

Type of Grant	Number of Respondents	Freq. of Responses	Hours per ^{1/} Response	Annual Burden
Discretionary	14,110	1	.25	3,528
Formula	1,530	1	.25	383
Fellowships	1,360	1	.25	109
Total Annual Hour Burden	17,000	1	.25	4,250

-If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

^{1/} The hours per response is estimated to be .25 of an hour which equates to 15 minutes.

-Provide estimates of annualized cost to respondents of the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

Table 2
Respondent's Annualized Cost

Respondent's Hourly Wage	Hours per Response	Cost to Respondent per Response
\$25.47 ^{2/}	.25	\$6.37

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14.)

-The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

-If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

-Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

No start-up, maintenance, and purchase of services costs will be incurred by the respondents.

^{2/} The hourly rate of \$25.47 is based on the 2001 General Pay Schedule of a GS-12, Step 1.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

**Table 3-A
AFEA Development Cost**

Hourly Rate	# of Hours	Total Cost
\$25.47	40	\$1,019

**Table 3-B
AFEA Printing Cost**

# of Applications	Per Unit Cost	Total Cost
5,000	.04	\$200

**Table 3-C
Processing Cost**

# of Applications	Per Unit Cost	Total Cost
17,000	.129	\$2,193

**Table 3-D
AFEA Data Entry Cost**

# of Applications	Per Unit Cost	Total Cost
17,000	1.197	\$20,341

**Table 3-E
AFEA Total Annualized Cost**

Cost Category	Costs
3-A. Development	\$1,019
3-B. Printing	\$200
3-E. Processing	\$2,193
3-D. Data Entry	\$20,341
Total	\$23,753

3/ The per unit cost is based on the 2001 hourly rate of a GS-7 (\$14.36) times the estimated cost of processing the application (.129).

4/ The per unit cost is based on the 2001 General Pay Schedule of a GS-7, Step 1 (\$14.36). It is estimated to take approximately 5 minutes per application to enter the data. The per unit rate is the hourly rate of \$14.36 divided by the number of minutes in an hour (60) = .2393. To determine the per unit cost multiply the per minute rate of .2393 by the number of minutes (5) it will take to enter the information for one respondent (1.197).

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

No program changes occurred.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

No plans exist to publish information collected for statistical use.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Not seeking approval for omission of expiration date.

18. Explain each exception to the certification statement identified in Item 20, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

Not seeking any exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

The agency should be prepared to justify its decision not to use statistical methods in any case where such methods might reduce burden or improve accuracy of results. When item 17 on Form OMB 83-I is checked "Yes," the following documentation should be included in the Supporting Statement to the extent that it applies to the methods proposed:

1. Describe the potential respondent universe (including a numerical estimate) and any sampling or other respondent selection method to be used. Data on the number of entities (e.g., establishments, state and local government units, households, or persons) in the universe covered by the collection and in the corresponding sample are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection.

Collection of information will not be used for statistical purposes.

2. Describe the procedures for the collection of information, including:

-Statistical methodology for stratification and sample selection.

-Estimation procedure.

-Degree of accuracy needed for the purpose described in the justification.

-Unusual problems requiring specialized sampling procedures, and

-Any use of periodic (less frequent than annual) data collection cycles to reduce burden.

Collection of information will not be used for statistical purposes.

3. Describe methods to maximize response and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield "reliable" data that can be generalized to the universe studied.

In order to maximize responses and address issues of non-responses, the questions and instructions are succinct and clear. Where a question is self-explanatory, no additional instructions are necessary; therefore, no instructions are provided. This method minimizes the need for an applicant to read unnecessary instructions.

4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections of information to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions from 10 or more respondents. A proposed test or set of tests may be submitted for approval separately or in combination with the main collection of information.

For this submission, no tests of procedures or methods will be undertaken.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other persons who will actually collect and/or analyze the information for the agency.

The AFEA is a data collection tool that will be used to facilitate in the determination of eligibility for the various ED discretionary grant programs. The AFEA is not designed as a data collection tool for the purpose of conducting statistical analysis.

Instructions for ED 424

1. **Legal Name and Address.** Enter the legal name of applicant and the name of the primary organizational unit which will undertake the assistance activity.
2. **D-U-N-S Number.** Enter the applicant's D-U-N-S Number. If your organization does not have a D-U-N-S Number, you can obtain the number by calling 1-800-333-0505 or by completing a D-U-N-S Number Request Form. The form can be obtained via the Internet at the following URL: <http://www.dnb.com>.
3. **Tax Identification Number.** Enter the tax identification number as assigned by the Internal Revenue Service.
4. **Catalog of Federal Domestic Assistance (CFDA) Number.** Enter the CFDA number and title of the program under which assistance is requested.
5. **Project Director.** Name, address, telephone and fax numbers, and e-mail address of the person to be contacted on matters involving this application.
6. **Federal Debt Delinquency.** Check "Yes" if the applicant's organization is delinquent on any Federal debt. (This question refers to the applicant's organization and not to the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.) Otherwise, check "No."
7. **Type of Applicant.** Enter the appropriate letter in the box provided.
8. **Novice Applicant.** Check "Yes" only if assistance is being requested under a program that gives special consideration to novice applicants and you meet the program requirements for novice applicants. By checking "Yes" the applicant certifies that it meets the novice applicant requirements specified by ED. Otherwise, check "No."
9. **Type of Submission.** Self-explanatory.
10. **Executive Order 12372.** Check "Yes" if the application is subject to review by Executive Order 12372. Also, please enter the month, date, and four (4) digit year (e.g., 12/12/2000). Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. Otherwise, check "No."
11. **Proposed Project Dates.** Please enter the month, date, and four (4) digit year (e.g., 12/12/2000).
12. **Human Subjects.** Check "Yes" or "No". If research activities involving human subjects are not planned at any time during the proposed project period, check "No." **The remaining parts of item 12 are then not applicable.**

If research activities involving human subjects, whether or not exempt from Federal regulations for the protection of human subjects, are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution,

check "Yes." If all the research activities are designated to be exempt under the regulations, enter, in item 12a, the exemption number(s) corresponding to one or more of the six exemption categories listed in "Protection of Human Subjects in Research" attached to this form. Provide sufficient information in the application to allow a determination that the designated exemptions in item 12a, are appropriate. **Provide this narrative information in an "Item 12/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page. Skip the remaining parts of item 12.**

If some or all of the planned research activities involving human subjects are covered (nonexempt), skip item 12a and continue with the remaining parts of item 12, as noted below. In addition, follow the instructions in "Protection of Human Subjects in Research" attached to this form to prepare the six-point narrative about the nonexempt activities. **Provide this six-point narrative in an "Item 12/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page.**

If the applicant organization has an approved Multiple Project Assurance of Compliance on file with the Grants Policy and Oversight Staff (GPOS), U.S. Department of Education, or with the Office for Protection from Research Risks (OPRR), National Institutes of Health, U.S. Department of Health and Human Services, that covers the specific activity, enter the Assurance number in item 12b and the date of approval by the Institutional Review Board (IRB) of the proposed activities in item 12c. This date must be no earlier than one year before the receipt date for which the application is submitted and must include the four (4) digit year (e.g., 2000). Check the type of IRB review in the appropriate box. An IRB may use the expedited review procedure if it complies with the requirements of 34 CFR 97.110. If the IRB review is delayed beyond the submission of the application, enter "Pending" in item 12c. If your application is recommended/selected for funding, a follow-up certification of IRB approval from an official signing for the applicant organization must be sent to and received by the designated ED official within 30 days after a specific formal request from the designated ED official. **If the applicant organization does not have** on file with GPOS or OPRR an **approved Assurance of Compliance** that covers the proposed research activity, enter "None" in item 12b and skip 12c. In this case, the applicant organization, by the signature on the application, is declaring that it will comply with 34 CFR 97 within 30 days after a specific formal request from the designated ED official for the Assurance(s) and IRB certifications.

13. **Project Title.** Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
14. **Estimated Funding.** Amount requested or to be contributed during the first funding/budget period by each contributor.

Additions and Deletions

Additions and Deletions:

--Additions:

None

--Deletions:

Deleted Novice Applicant--item #7 [?] #8

*This was item #8
on the old form
(see attached)*

Appendix A-Application for Federal Education Assistance

Application for Federal Education Assistance



U.S. Department of Education

Form Approved
OMB No. 1875-0106
Exp. 06/30/2004

Applicant Information

1. Name and Address

Legal Name: _____

Address: _____

Organizational Unit

City _____

State _____

County _____

ZIP Code + 4 _____

2. Applicant's D-U-N-S Number

--	--	--	--	--	--	--	--	--	--	--	--

6. Is the applicant delinquent on any Federal debt? Yes No

(If "Yes," attach an explanation.)

3. Applicant's T-I-N

--	--	--	--	--	--	--	--	--	--	--	--

Title: _____

4. Catalog of Federal Domestic Assistance #:

8	4										
---	---	--	--	--	--	--	--	--	--	--	--

5. Project Director: _____

7. Type of Applicant (Enter appropriate letter in the box.)

Address: _____

- A State H Independent School District
- B County I Public College or University
- C Municipal J Private, Non-Profit College or University
- D Township K Indian Tribe
- E Interstate L Individual
- F Intermunicipal M Private, Profit-Making Organization
- G Special District N Other (Specify): _____

City _____ State _____ ZIP Code + 4 _____

Tel. #: () _____ - _____ Fax #: () _____ - _____

E-Mail Address: _____

Application Information

8. Type of Submission:

—PreApplication

—Application

- Construction Construction
- Non-Construction Non-Construction

11. Are any research activities involving human subjects planned at any time during the proposed project period? Yes No

a. If "Yes," Exemption(s) #: _____

b. Assurance of Compliance #: _____

OR

9. Is application subject to review by Executive Order 12372 process?

- Yes (Date made available to the Executive Order 12372 process for review): ____/____/____
- No (If "No," check appropriate box below.)
 - Program is not covered by E.O. 12372.
 - Program has not been selected by State for review.

c. IRB approval date: _____ { Full IRB or Expedited Review

10. Proposed Project Dates: _____ / _____ / _____

Start Date: _____ / _____ / _____	End Date: _____ / _____ / _____
-----------------------------------	---------------------------------

12. Descriptive Title of Applicant's Project:

Estimated Funding		
13a. Federal	\$.00
b. Applicant	\$.00
c. State	\$.00
d. Local	\$.00
e. Other	\$.00
f. Program Income	\$.00
g. TOTAL	\$.00

Authorized Representative Information

14. To the best of my knowledge and belief, all data in this preapplication/application are true and correct. The document has been duly authorized by the governing body of the applicant and the applicant will comply with the attached assurances if the assistance is awarded.

a. Typed Name of Authorized Representative _____

b. Title _____

c. Tel. #: () _____ - _____ Fax #: () _____ - _____

d. E-Mail Address: _____

e. Signature of Authorized Representative _____ Date: ____/____/____

1. **Legal Name and Address.** Enter the legal name of applicant and the name of the primary organizational unit which will undertake the assistance activity.
2. **D-U-N-S Number.** Enter the applicant's D-U-N-S Number. If your organization does not have a D-U-N-S Number, you can obtain the number by calling 1-800-333-0505 or by completing a D-U-N-S Number Request Form. The form can be obtained via the Internet at the following URL: <http://www.dnb.com>.
3. **Taxpayer Identification Number.** Enter the taxpayers's identification number as assigned by the Internal Revenue Service.
4. **Catalog of Federal Domestic Assistance (CFDA) Number.** Enter the CFDA number and title of the program under which assistance is requested.
5. **Project Director.** Name, address, telephone and fax numbers, and e-mail address of the person to be contacted on matters involving this application.
6. **Federal Debt Delinquency.** Check "Yes" if the applicant's organization is delinquent on any Federal debt. (This question refers to the applicant's organization and not to the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.) Otherwise, check "No."
7. **Type of Applicant.** Enter the appropriate letter in the box provided.
8. **Type of Submission.** Self-explanatory.
9. **Executive Order 12372.** Check "Yes" if the application is subject to review by Executive Order 12372. Also, please enter the month, date, and four (4) digit year (e.g., 12/12/2001). Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. Otherwise, check "No."
10. **Proposed Project Dates.** Please enter the month, date, and four (4) digit year (e.g., 12/12/2001).
11. **Human Subjects.** Check "Yes" or "No". If research activities involving human subjects are not planned at any time during the proposed project period, check "No." **The remaining parts of item 11 are then not applicable.**

If research activities involving human subjects, whether or not exempt from Federal regulations for the protection of human subjects, are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check "Yes." If all the research activities are designated to be exempt under the regulations, enter, in item 11a, the exemption number(s) corresponding to one or more of the six exemption categories listed in "Protection of Human Subjects in Research" attached to this form. Provide sufficient information in the application to allow a determination that the designated exemptions in item 11a, are appropriate. **Provide this narrative information in an "Item 11/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page. Skip the remaining parts of item 11.**

If some or all of the planned research activities involving human subjects are covered (nonexempt), skip item 11a and continue with the remaining parts of item 11, as noted below. In addition, follow the instructions in "Protection of Human Subjects in Research" attached to this form to prepare the six-point narrative about the nonex-

empt activities. **Provide this six-point narrative in an "Item 11/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page.**

If the applicant has an approved Federal-wide or Multiple Project Assurance of Compliance on file with the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, that covers the specific activity, enter the Assurance number in item 11b. Institutional Review Board (IRB) approval is not required when the application is filed. However, if the IRB has approved the proposed activities, enter the IRB approval date in item 11c and check the type of IRB review, full or expedited, in the appropriate box. (An IRB may use the expedited review procedure if it complies with the requirements of 34 CFR 97.110.) If the IRB review is pending, enter "Pending" in item 11c. If the application is recommended/selected for funding, the designated ED official will request that the applicant send the IRB approval(s) within 30 days after the specific formal request.

If the applicant does not have an approved Assurance of Compliance that covers the proposed research activity, enter "None" in item 11b and skip 11c. In this case, the applicant, by the signature on the application, is declaring that it will comply with 34 CFR 97 within 30 days after a specific formal request from the designated ED official for the Assurance(s) and IRB certifications.

12. **Project Title.** Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
13. **Estimated Funding.** Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 13.
14. **Certification.** To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office.

Be sure to enter the telephone and fax number and e-mail address of the authorized representative. Also, in item 14e, please enter the month, date, and four (4) digit year (e.g., 12/12/2001) in the date signed field.

Paperwork Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is **1875-0106**. The time required to complete this information collection is estimated to average between 15 and 45 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. **If you have any comments concerning the accuracy of the estimate(s) or suggestions for improving this form, please write to:** U.S. Department of Education, Washington, D.C. 20202-4651. **If you have comments or concerns regarding the status of your individual submission of this form write directly to:** Joyce I. Mays, Application Control Center, U.S. Department of Education, 7th and D Streets, S.W. ROB-3, Room 3633, Washington, D.C. 20202-4725.

PROTECTION OF HUMAN SUBJECTS IN RESEARCH

(Attachment to ED 424)

I. Instructions to Applicants about the Narrative Information that Must be Provided if Research Activities Involving Human Subjects are Planned

If you marked item 11 on the application "Yes" and designated exemptions in 11a, (**all research activities are exempt**), provide sufficient information in the application to allow a determination that the designated exemptions are appropriate. Research involving human subjects that is exempt from the regulations is discussed under **II.B. "Exemptions,"** below. The Narrative must be succinct. **Provide this information in an "Item 11/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page.**

If you marked "Yes" to item 11 on the face page, and designated no exemptions from the regulations (**some or all of the research activities are nonexempt**), address the following six points for each nonexempt activity. In addition, if research involving human subjects will take place at collaborating site(s) or other performance site(s), provide this information before discussing the six points. Although no specific page limitation applies to this section of the application, be succinct. Provide the six-point narrative and discussion of other performance sites in an **"Item 11/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page.**

(1) Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

(2) Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

(3) Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and

obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

(4) Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

(5) Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

(6) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

II. Information on Research Activities Involving Human Subjects

A. Definitions.

A research activity involves human subjects if the activity is research, as defined in the Department's regulations, and the research activity will involve use of human subjects, as defined in the regulations.

—Is it a research activity?

The ED Regulations for the Protection of Human Subjects, Title 34, Code of Federal Regulations, Part 97, define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." *If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research.* Activities which meet this definition constitute research 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.

—Is it a human subject?

The regulations define human subject as “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.” (1) *If an activity involves obtaining information about a living person by manipulating that person or that person’s environment, as might occur when a new instructional technique is tested, or by communicating or interacting with the individual, as occurs with surveys and interviews, the definition of human subject is met.* (2) *If an activity involves obtaining private information about a living person in such a way that the information can be linked to that individual (the identity of the subject is or may be readily determined by the investigator or associated with the information), the definition of human subject is met.* [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 school health record).]

B. Exemptions.

Research activities in which the only involvement of human subjects will be in one or more of the following six categories of *exemptions* are not covered by the regulations:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) 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: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) 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. *If the subjects are children, this exemption applies only to research involving educational tests or observations of*

public behavior when the investigator(s) do not participate in the activities being observed. [Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted.]

- (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 section (2) above, if the human subjects are elected or appointed public officials or candidates for public office; or 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 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: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) 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, (a) if wholesome foods without additives are consumed or (b) 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.

Copies of the Department of Education’s Regulations for the Protection of Human Subjects, 34 CFR Part 97 and other pertinent materials on the protection of human subjects in research are available from the Grants Policy and Oversight Staff (GPOS) Office of the Chief Financial and Chief Information Officer, U.S. Department of Education, Washington, D.C., telephone: (202) 708-8263, and on the U.S. Department of Education’s Protection of Human Subjects in Research Web Site at <http://ocfo.ed.gov/humansub.htm>.

Appendix B--OMB Circular A-102

A-102: Grants and Cooperative Agreements with State and Local Governments
53 FR 8028 March 11, 1988

OFFICE OF MANAGEMENT AND BUDGET

AGENCY: Office of Management and Budget.

A-102: Grants and Cooperative Agreements with State and Local Governments

ACTION: Revision of Circular A-102.

SUMMARY: This notice sets forth the final revision of Office of Management and Budget Circular A-102, "Grants and Cooperative Agreements with State and Local Governments".

FOR FURTHER INFORMATION CONTACT: Jonathan Breul, Financial Management Division, Office of Management and Budget, Washington, DC 20503. (202) 395-3050.

SUPPLEMENTARY INFORMATION: An interagency task force under the President's Council on Management Improvement (PCMI) was established to review existing guidance for managing Federal aid programs. On June 18, 1984, OMB published a Notice in the Federal Register (49 FR 24958) announcing the review and seeking public comment on over 50 issues and possible options for each. Federal agencies, States, local governments, interest groups, business organizations, and nonprofit organizations, as well as members of Congress submitted several hundred comments.

Five agency-chaired teams studied the comments, Circular A-102, and the existing Federal agency regulations implementing it to develop and draft two products: a revised OMB Circular -- addressed solely to Federal agencies, and a "common" government-wide regulation -- addressed to State and local grantees. The proposed government-wide "common rule" stated the fiscal and administrative conditions governing grants to State and local governments and subgrantees which are State and local governments.

On March 12, 1987, the President directed OMB to revise Circular A-102 and all affected Federal agencies to simultaneously propose a common rule to adopt verbatim government-wide grants management terms and conditions. The revised Circular and common rule were to be proposed within 90 days, and issued final within one year.

OMB published a proposed revision to Circular A-102 as a Notice in the June 9, 1987 issue of the Federal Register (52 FR 21816-21818). Simultaneously in the same issue (52 FR 21820-21852), Federal grant-making agencies proposed a common rule.

Comments and Changes to the Proposed Revision

While OMB and the agencies received nearly 100 comments on the proposed common rule, only a handful addressed the revision to Circular A-102 itself.

Advance Public Notice and Priority Setting (paragraph 6b).

A number of Federal agencies questioned the need for, and type of official responsible for, advance public notice and priority setting in discretionary grant and cooperative agreement programs. Consistent with recent recommendations by the U.S. General Accounting Office (GAO) ("Discretionary Grants: Opportunities to Improve Federal Discretionary Award Practices"), this section aims to improve managerial accountability for the discretionary award process by emphasizing the need for upfront priority setting and policy-level sign-off on grant and cooperative agreement awards. "Policy-level official" was deliberately not defined in order for agency heads to determine the appropriate placement of such responsibilities. Such officials include program heads or political appointees located sufficiently high in an organization to ensure that funding priorities and actual awards are consistent with the agency's overall priorities. OMB is willing to work with agencies to identify appropriate officials where there is question.

Standard Forms for Applying for Federal Assistance (paragraph 6c).

Several Federal agencies, particularly those with programs which fund both governmental (State and local) and nonprofit grantees, requested not to use the standard application facesheet (SF-424) as well as the project approval checklist, budget sheet, and standard assurances in Attachment "M" to Circular A-102. They pointed out that unlike 1971, when Circular A-102 and the forms were originally developed, there is less duplication and overlap in Federal funding for grantees and consequently less need by grantees for uniform application forms. Further, OMB now reviews and approves all forms and application packages under the Paperwork Reduction Act of 1980. In recognition of these changes in the makeup of Federal assistance programs, the types of recipients receiving funding and the paperwork control authorities in OMB's Office of Information and Regulatory Affairs (OIRA), OMB asked for public comment on revised standard application forms in a May 29, 1987 Notice in the Federal Register (52 20178-20179).

The great majority of the over 80 public comments to the May 1987 Notice were concerned about the proposed financial reporting formats for the open-ended entitlement programs, rather than either the need for, or design of, the standard application forms. We attribute much of this lack of interest to the fact that, with the approval of OMB's Office of Information and Regulatory Affairs, few programs use the forms displayed in Circular A-102 "as is". In fact, aside from the SF-424 Facesheet, nearly every program extensively tailors the forms or develops its own instructions and supplemental program-specific requirements.

In recognition of current practice and approved forms, the proposed circular has been revised to require use of either (1) three types of pre-approved standard forms: facesheet, standard budget information (construction or non-construction) and standard assurances (construction or non-construction) or (2) forms approved by OMB under the Paperwork Reduction Act of 1980. Two forms previously displayed in Circular A-102, the Part II, "Project Approval Checklist," and Part IV, "Narrative," are eliminated. The contents of the latter are reflected as guidance to agencies in paragraph 6c. of the circular. Agencies are free to use the standard forms without further OMB clearance. Use of any other forms and application packages requires OMB approval and clearance under the Paperwork Reduction Act of 1980.

Exception to the common rule (paragraph 6g).

A number of grantees expressed concern that paragraph 6g, "Special Conditions or Restrictions,"

coupled with the corresponding "Exceptions" (§____.6) and "High-Risk" (§____.12) provisions of the common rule are loopholes which permit Federal agencies to circumvent the rule and impose additional or unwarranted requirements. In recognition of this concern and to permit oversight, the circular is revised to make it clear that agencies will document the use of these provisions.

Financial Status Reports (paragraph 7c).

A new section was added to require use of the SF-269, Financial Status Report-Long Form, or SF-269a, Financial Status Report-Short Form. These forms are a revision of the SF-269 previously required under Circular A-102, with changes based on a May 29, 1987 Federal Register Notice (discussed above under "Standard Forms for Applying for Federal Assistance"). Both the short and long forms are simplified to require a single column rather than 6-column breakout of the status of funds. The long form responds to recommendations from the GAO for a form which permits reporting matching as well as the various uses of program income. The new paragraph 7c. expresses a longstanding, but unstated, prohibition against agencies using the form to collect object class expenditure data (e.g., expenditures broken down by personnel, travel, equipment, etc.). Further, it limits collection of expenditure detail by programs, functions or activities within the program or project, unless required by statute or regulation.

Contracting with small and minority firms, women's business enterprise and labor surplus area firms (paragraph 7d).

A number of commenters expressed concern that the proposed circular did not contain policy language from the old Circular A-102 which encouraged use of small, minority, women's and labor surplus area firms. This was true because all of the substantive requirements from Attachment "O" in the old A-102 for grantees to use such firms when possible were proposed to be codified in the June 9, 1988, 24-agency, common rule. Unfortunately, in the interest of streamlining the rule, the prefatory sentence explaining that this is national policy was dropped. To remove any doubt that grantees are encouraged to contract with such firms, the opening sentence concerning small and minority business, as well as those concerning women's enterprises and labor surplus area firms have been restored to the circular.

Program Income (paragraph 7e).

A number of State and local grantees were concerned that agencies will only sparingly permit the use of the addition or matching share alternatives for use of program income. On the other hand, others such as the GAO supported the circular, stating that there should be a preference for deducting program income from program costs since this alternative will result in financial savings to the Federal Government and grantees. No change is made to the proposed circular. In the event this provision serves as a disincentive to earning such income, §____.25(g) of the common rule permits agencies to specify another alternative (or combination of alternatives) in program regulations or a specific grant agreement.

Site visits and technical assistance (paragraph 7f).

Federal agencies expressed concern that the proposal would unduly restrict their ability to travel to grantee project sites or offer technical assistance. OMB proposed site visits "only as warranted by program or project needs" and restricted technical assistance visits "only (1) in response to requests from recipients, or (2) when recipients are designated 'high risk.'" The proposed

approach represented a departure from the original Circular A-102 which "encouraged" agencies to travel and offer technical assistance. Frequent travel and gratuitous technical assistance are no longer realistic given the Federal budget deficit and they are inconsistent with Federal deference to States' authority and competence under Federalism. However, to enable Federal agencies to address genuine program needs, an additional justification for technical assistance visits has been added based on "demonstrated program need."

Property Management (paragraph 8a).

A number of commenters misinterpreted the provisions of the closeout provisions of the circular (as well as the property sections of the common rule) dealing with "federally owned property". They mistakenly concluded these provisions covered all grant-acquired property and equipment, not just that which is Federally owned and provided. This is not so because title to grant-acquired property vests with the grantee, not the Federal Government. The circular and common rule have been changed to make this distinction clear.

Another commenter suggested that closeout review cover all non-expendable personal property purchased with grant funds where title rests with the recipient. We do not believe such a mandatory Federal review of grant-acquired property is warranted. The common rule contains explicit instructions as to the grantee's property records and calls for the grantee to perform a physical inventory at least once every two years.

Closeout (paragraph 8a).

One agency expressed the opinion that Section 8a requiring written notification to grantees of required closeout documents may be too staff intensive. The agency recommended that published program regulations detailing this requirement should be sufficient. We agree. Since closeout reports do not generally vary significantly, a published program regulation or standard notice can satisfy the requirement.

[Circular No. A-102 (Revised)]

March 3, 1988.

To the Heads of Executive Departments and Establishments

Subject: Grants and Cooperative Agreements with State and Local Governments

1. Purpose. This Circular establishes consistency and uniformity among Federal agencies in the management of grants and cooperative agreements with State, local, and federally recognized Indian tribal governments. This revision supersedes Office of Management and Budget (OMB) Circular No. A-102, dated January 1981.
2. Authority. This Circular is issued under the authority of the Budget and Accounting Act of 1921, as amended; the Budget and Accounting Procedures Act of 1950, as amended; Reorganization Plan No. 2 of 1970; and Executive Order 11541. Also included in the Circular are standards to ensure consistent implementation of sections 202, 203, and 204 of the Intergovernmental Cooperation Act of 1968, the Office of Federal Procurement Policy Act Amendments of 1983, and sections 6301-08, title 31, United States Code.

3. Background. On March 12, 1987, the President directed all affected agencies to issue a grants management common rule to adopt government-wide terms and conditions for grants to State and local governments. This revised Circular provides guidance to Federal agencies on business-like management of grant programs and other matters not covered in the common rule. The revision replaces and rescinds Circular A-102, dated January 1981, including Attachments A-P.
4. Coverage. Consistent with their legal obligations, all Federal agencies administering programs that involve grants and cooperative agreements with State, local and Indian tribal governments (grantees) shall follow the policies in this Circular and issue a common grants management rule (common rule). If the enabling legislation for a specific grant program prescribes policies or requirements that differ from those in this Circular, the provisions of the enabling legislation shall govern.
5. Deviations. The Office of Management and Budget may grant deviations from the requirements of this Circular when permissible under existing law. However, in the interest of uniformity and consistency, deviations will be permitted only in exceptional circumstances.
6. Pre-Award Policies.
 - a. Use of grants and cooperative agreements. Sections 6301-08, title 31, United States Code govern the use of grants, contracts and cooperative agreements. A grant or cooperative agreement shall be used only when the principal purpose of a transaction is to accomplish a public purpose of support or stimulation authorized by Federal statute. Contracts shall be used when the principal purpose is acquisition of property or services for the direct benefit or use of the Federal Government. The statutory criterion for choosing between grants and cooperative agreements is that for the latter, "substantial involvement is expected between the executive agency and the State, local government, or other recipient when carrying out the activity contemplated in the agreement."
 - b. Advance Public Notice and Priority Setting.
 - (1) Federal agencies shall provide the public with an advance notice in the Federal Register, or by other appropriate means, of intended funding priorities for discretionary assistance programs, unless funding priorities are established by Federal statute. These priorities shall be approved by a policy level official.
 - (2) Whenever time permits, agencies shall provide the public an opportunity to comment on intended funding priorities.
 - (3) All discretionary grant awards in excess of \$25,000 shall be reviewed for consistency with agency priorities by a policy level official.
 - c. Standard Forms for Applying for Grants and Cooperative Agreements.
 - (1) Agencies shall use the following standard application forms unless they obtain OMB approval under the Paperwork Reduction Act of 1980 (44 U.S.C. 35) and the 5 CFR Part 1320, "Controlling Paperwork Burdens on the Public":

SF-424 Facesheet

SF-424a Budget Information (Non-Construction)

SF-424b Budget Information (Construction)

SF-424c Standard Assurances (Non-Construction)

-- SF-424d Standard Assurances (Construction)

When different or additional information is needed to comply with legislative requirements or to meet specific program needs, agencies shall also obtain prior OMB approval.

- (2) A preapplication shall be used for all construction, land acquisition and land development projects or programs when the need for Federal funding exceeds \$100,000, unless the Federal agency determines that a preapplication is not needed. A preapplication is used to:
 - (a) Establish communication between the agency and the applicant,
 - (b) Determine the applicant's eligibility,
 - (c) Determine how well the project can compete with similar projects from others, and
 - (d) Discourage any proposals that have little or no chance for Federal funding before applicants incur significant costs in preparing detailed applications.
- (3) Agencies shall use the Budget Information (Construction) and Standard Assurances (Construction) when the major purpose of the project or program is construction, land acquisition or land development.
- (4) Agencies may specify how and whether budgets shall be shown by functions or activities within the program or project.
- (5) Agencies should generally include a request for a program narrative statement which is based on the following instructions:
 - (a) Objectives and need for assistance. Pinpoint any relevant physical, economic, social, financial, institutional, or other problems requiring a solution. Demonstrate the need for the assistance and state the principal and subordinate objectives of the project. Supporting documentation or other testimonies from concerned interests other than the applicant may be used. Any relevant data based on planning studies should be included or footnoted.
 - (b) Results or Benefits Expected. Identify results and benefits to be derived. For example, show how the facility will be used. For land acquisition or development projects, explain how the project will benefit the public.
 - (c) Approach. Outline a plan of action pertaining to the scope and detail how the proposed work will be accomplished for each assistance program. Cite factors which might accelerate or decelerate the work and your reasons for taking this approach as opposed to others. Describe any unusual features of the project, such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvements. Provide for each assistance program

quantitative projections of the accomplishments to be achieved, if possible. When accomplishments cannot be quantified, list the activities in chronological order to show the schedule of accomplishments and their target dates. Identify the kinds of data to be collected and maintained, and discuss the criteria to be used to evaluate the results and success of the project. Explain the methodology that will be used to determine if the needs identified and discussed are being met and if the results and benefits identified are being achieved. List each organization, cooperator, consultant, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

- (d) Geographic Location. Give a precise location of the project and area to be served by the proposed project. Maps or other graphic aids may be attached.
 - (e) If applicable, provide the following information: for research and demonstration assistance requests, present a biographical sketch of the program director with the following information: name, address, telephone number, background, and other qualifying experience for the project. Also, list the name, training and background for other key personnel engaged in the project. Describe the relationship between this project and other work planned, anticipated, or underway under Federal assistance. Explain the reason for all requests for supplemental assistance and justify the need for additional funding. Discuss accomplishments to date and list in chronological order a schedule of accomplishments, progress or milestones anticipated with the new funding request. If there have been significant changes in the project objectives, location, approach or time delays, explain and justify. For other requests for changes, or amendments, explain the reason for the change(s). If the scope or objectives have changed or an extension of time is necessary, explain the circumstances and justify. If the total budget has been exceeded or if the individual budget items have changes more than the prescribed limits, explain and justify the change and its effect on the project.
- (6) Additional assurances shall not be added to those contained on the standard forms, unless specifically required by statute.
- d. Debarment and Suspension. Federal agencies shall not award assistance to applicants that are debarred or suspended, or otherwise excluded from or ineligible for participation in Federal assistance programs under Executive Order 12549. Agencies shall establish procedures for the effective use of the Consolidated List of Debarred, Suspended, Voluntarily Excluded and Ineligible Assistance Participants to assure that they do not award assistance to listed parties in violation of the Executive Order. Agencies shall also establish procedures to provide for effective use and/or dissemination of the list to assure that their grantees and subgrantees (including contractors) at any tier do not make awards in violation of implementing regulations.
- e. Awards and Adjustments.
- (1) Ordinarily awards shall be made at least ten days prior to the beginning of the grant period.
 - (2) Agencies shall notify grantees immediately of any anticipated adjustments in the amount of an award. This notice shall be provided as early as possible in the funding period. Reductions in funding shall apply only to periods after notice is provided. Whenever an agency adjusts the amount of an award, it shall also make an appropriate adjustment to the amount of any required matching or cost sharing.

- f. Carryover Balances. Agencies shall be prepared to identify to OMB the amounts of carryover balances (e.g., the amounts of estimated, grantee unobligated balances available for carryover into subsequent grant periods). This presentation shall detail the fiscal and programmatic (level of effort) impact in the following period.
- g. Special Conditions or Restrictions. Agencies may impose special conditions or restrictions on awards to "high risk" applicants/grantees in accordance with § ____.12 of the common rule. Agencies shall document use of the "Exception" provisions of § ____.6 and "High-risk" provisions of § ____.12 of the common rule.
- h. Waiver of Single State Agency Requirements.
 - (1) Requests to agencies from the Governors, or other duly constituted State authorities, for waiver of "single" State agency requirements in accordance with section 6504, title 31, United States Code, shall be given expeditious handling and, whenever possible, an affirmative response.
 - (2) When it is necessary to refuse a request for waiver of "single" State agency requirements under section 204, the Federal grantor agency shall advise the Office of Management and Budget prior to informing the State that the request cannot be granted. The agency shall indicate to OMB the reasons for the denial of the request.
 - (3) Legislative proposals embracing grant-in-aid programs shall avoid inclusion of proposals for "single" State agencies in the absence of compelling reasons to do otherwise. In addition, existing requirements in present grant-in-aid programs shall be reviewed and legislative proposals developed for the removal of these restrictive provisions.
- i. Patent Rights. Agencies shall use the standard patent rights clause specified in "Rights to Inventions made by Nonprofit Organizations and Small Business Firms" (37 CFR Part 401), when providing support for research and development.

7. Post-award Policies.

- a. Cash Management. Agency methods and procedures for transferring funds shall minimize the time elapsing between the transfer to recipients of grants and cooperative agreements and the recipient's need for the funds.
 - (1) Such transfers shall be made consistent with program purpose, applicable law and Treasury regulations at 31 CFR Part 205.
 - (2) Where letters-of-credit are used to provide funds, they shall be in the same amount as the award.
- b. Grantee Financial Management Systems. In assessing the adequacy of an applicant's financial management system, the awarding agency shall rely on readily available sources of information such as audit reports to the maximum extent possible. If additional information is necessary to assure prudent management of agency funds, it shall be obtained from the applicant or from an on-site review.
- c. Financial Status Reports.

- (1) Federal agencies shall require grantees to use the SF-269, Financial Status Report-Long Form, or SF-269a, Financial Status Report-Short Form, to report the status of funds for all nonconstruction projects or programs. Federal agencies need not require the Financial Status Report when the SF-270, Request for Advance or Reimbursement, or SF-272, Report of Federal Cash Transactions, is determined to provide adequate information.
 - (2) Federal agencies shall not require grantees to report on the status of funds by object class category or expenditure (e.g., personnel, travel, equipment).
 - (3) If reporting on the status of funds by programs, functions or activities within the project or program is required by statute or regulation, Federal agencies shall instruct grantees to use block 12, Remarks, on the SF-269 or a supplementary form approved by the OMB under the Paperwork Reduction Act of 1980.
 - (4) Federal agencies shall prescribe whether the reporting shall be on a cash or an accrual basis. If the Federal agency requires accrual information and the grantee's accounting records are not normally kept on an accrual basis, the grantee shall not be required to convert its accounting system but shall develop such accrual information through an analysis of the documentation on hand.
- d. Contracting With Small and Minority Firms, Women's Business Enterprise and Labor Surplus Area Firms. It is national policy to award a fair share of contracts to small and minority business firms. Grantees shall take similar appropriate affirmative action to support of women's enterprises and are encouraged to procure goods and services from labor surplus areas.
- e. Program Income.
- (1) Agencies shall encourage grantees to generate program income to help defray program costs. However, Federal agencies shall not permit grantees to use grant-acquired equipment to compete unfairly with the private sector.
 - (2) Federal agencies shall instruct grantees to deduct program income from total program costs as specified in the common rule at § ____.25(g)(1), unless agency regulations or the terms of the grant award state otherwise. Authorization for recipients to follow the other alternatives in § ____.25(g)(2) and (3) shall be granted sparingly.
- f. Site Visits and Technical Assistance. Agencies shall conduct site visits only as warranted by program or project needs. Technical assistance site visits shall be provided only (1) in response to requests from grantees, (2) based on demonstrated program need, or (3) when recipients are designated "high risk" under § ____.12 of the common rule.

8. After-the-grant Policies.

- a. Closeout. Federal agencies shall notify grantees in writing before the end of the grant period of final reports that shall be due, the dates by which they must be received, and where they must be submitted. Copies of any required forms and instructions for their completion shall be included with this notification. The Federal actions that must precede closeout are:
 - (1) Receipt of all required reports,

- (2) Disposition or recovery of federally-owned assets (as distinct from property acquired under the grant), and
 - (3) Adjustment of the award amount and the amount of Federal cash paid the recipient.
- b. Annual Reconciliation of Continuing Assistance Awards. Federal agencies shall reconcile continuing awards at least annually and evaluate program performance and financial reports.

Items to be reviewed include:

- (1) A comparison of the recipient's work plan to its progress reports and project outputs,
- (2) the Financial Status Report (SF-269),
- (3) Request(s) for payment,
- (4) Compliance with any matching, level of effort or maintenance of effort requirement, and
- (5) A review of federally-owned property (as distinct from property acquired under the grant).

9. Entitlements (Reserved)

10 Policy Review (Sunset). The Circular will have a policy review three years from the date of issuance.

11 Effective Date. The Circular is effective on publication.

12 Inquiries. Further information concerning this Circular may be obtained from: Financial Management Division, New Executive Office Building, Room 10215, Office of Management and Budget, Washington, DC 20503, (202) 395-3050.

James C. Miller III,

**Appendix C - CFR 34 Part 74--Administration of Grants and Agreements
with Institutions of Higher Education, Hospitals, and Other Non-Profit
Organizations**

**PART 74—ADMINISTRATION OF
GRANTS AND AGREEMENTS WITH
INSTITUTIONS OF HIGHER EDU-
CATION, HOSPITALS, AND OTHER
NON-PROFIT ORGANIZATIONS**

Subpart A—General

- Sec.
74.1 Purpose.
74.2 Definitions.
74.3 Effect on other issuances.
74.4 Deviations.
74.5 Subawards.

Subpart B—Pre-Award Requirements

- 74.10 Purpose.
74.11 Pre-award policies.
74.12 Forms for applying for Federal assist-
ance.
74.13 Debarment and suspension.
74.14 Special award conditions.
74.15 Metric system of measurement.
74.16 Resource Conservation and Recovery
Act.
74.17 Certifications and representations.

Subpart C—Post-Award Requirements

Financial and Program Management

- 74.20 Purpose of financial and program man-
agement.
74.21 Standards for financial management
systems.
74.22 Payment.
74.23 Cost sharing or matching.
74.24 Program income.
74.25 Revision of budget and program plans.
74.26 Non-Federal audits.
74.27 Allowable costs.
74.28 Period of availability of funds.

Property Standards

- 74.30 Purpose of property standards.
74.31 Insurance coverage.
74.32 Real property.
74.33 Federally-owned and exempt property.
74.34 Equipment.
74.35 Supplies and other expendable prop-
erty.
74.36 Intangible property.
74.37 Property trust relationship.

Procurement Standards

- 74.40 Purpose of procurement standards.
74.41 Recipient responsibilities.
74.42 Codes of conduct.
74.43 Competition.
74.44 Procurement procedures.
74.45 Cost and price analysis.
74.46 Procurement records.
74.47 Contract administration.
74.48 Contract provisions.

Reports and Records

- 74.50 Purpose of reports and records.
74.51 Monitoring and reporting program
performance.
74.52 Financial reporting.
74.53 Retention and access requirements for
records.

Termination and Enforcement

- 74.60 Purpose of termination and enforce-
ment.
74.61 Termination.
74.62 Enforcement.

Subpart D—After-the-Award Requirements

- 74.70 Purpose.
74.71 Closeout procedures.
74.72 Subsequent adjustments and contin-
uing responsibilities.
74.73 Collection of amounts due.

**APPENDIX A TO PART 74—CONTRACT PROVI-
SIONS**

AUTHORITY: 20 U.S.C. 1221e-3(a)(1) and 3474;
OMB Circular A-110, unless otherwise noted.

SOURCE: 59 FR 34724, July 5, 1994, unless
otherwise noted.

Program income. Except as otherwise provided in ED regulations or the award, program income does not include the return of principal on loans, rebates, discounts, etc., or interest earned on any of them.

Project costs means all allowable costs, as established in the applicable Federal cost principles, incurred by a recipient for the purpose of the contract or subaward, including the direct and indirect costs of the award during the project period.

Project period means the period established in the award document during which Federal sponsorship begins and ends.

Property means, unless otherwise defined, real property, equipment, intangible property and debt instruments.

Real property means land, including improvements, structures and appurtenances thereon, but excludes movable machinery and equipment.

Recipient means an organization receiving financial assistance directly or indirectly from the Secretary or ED to carry out a project or program. The term includes public and private institutions of higher education, public and private hospitals, other quasi-public and private non-profit organizations such as, but not limited to, community action agencies, research institutes, educational associations, and health centers. The term includes commercial organizations, foreign or international organizations, and agencies of the United States which are recipients, subrecipients, or contractors of recipients at the discretion of the Secretary. The term does not include government-owned contractor-operated facilities or research centers providing financial support for mission-oriented, large-scale programs that are government-owned or controlled, or are designated as federally-funded research and development centers.

Research and development means all research activities, both basic and applied, and all development activities that are supported at universities, colleges, and other non-profit institutions. "Research" is defined as a systematic study directed toward fuller

scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes. The term "research" also includes activities involving the training of individuals in research techniques where these activities utilize the same facilities as other research and development activities and where these activities are not included in the instruction function.

Small awards means a grant or cooperative agreement not exceeding the small purchase threshold fixed at 41 U.S.C. 403(1) (currently \$25,000).

Subaward means an award of financial assistance in the form of money or property in lieu of money, made under an award by a recipient to an eligible subrecipient or by a subrecipient to a lower tier subrecipient. The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract, but does not include procurement of goods and services nor does it include any form of assistance which is excluded from the definition of "award" as defined in this section.

Subrecipient means the legal entity to which a subaward is made and which is accountable to the recipient for the use of the funds provided. The term may include foreign or international organizations (such as agencies of the United States) at the discretion of the Secretary.

Supplies means all personal property, excluding equipment, intangible property, and debt instruments as defined in this section, and inventions of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement ("subject inventions"), as defined in 37 CFR Part 401—Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements.

Suspension means an action by the Secretary that temporarily withdraws Federal sponsorship under an award, pending corrective action by the recipient or pending a decision to terminate

the award by the Secretary. Suspension of an award is a separate action from suspension under 34 CFR Part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

Termination means the cancellation of Federal sponsorship, in whole or in part, under an agreement at any time prior to the date of completion.

Third party in-kind contributions means the value of non-cash contributions provided by non-Federal third parties. Third party in-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and the value of goods and services directly benefiting and specifically identifiable to the project or program.

Unliquidated obligations, for financial reports prepared on a cash basis, means the amount of obligations incurred by the recipient that have not been paid. For reports prepared on an accrued expenditure basis, they represent the amount of obligations incurred by the recipient for which an outlay has not been recorded.

Unobligated balance means the portion of the funds authorized by the Secretary that has not been obligated by the recipient and is determined by deducting the cumulative obligations from the cumulative funds authorized.

Unrecovered indirect cost means the difference between the amount awarded and the amount which could have been awarded under the recipient's approved negotiated indirect cost rate.

Working capital advance means a procedure whereby funds are advanced to the recipient to cover its estimated disbursement needs for a given initial period.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.3 Effect on other issuances.

For awards subject to this part, all administrative requirements of codified program regulations, program manuals, handbooks, and other non-regulatory materials which are inconsistent with the requirements of this part are superseded, except to the extent they are required by statute, or

authorized in accordance with the deviations provision in § 74.4.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.4 Deviations.

The Secretary, after consultation with the Office of Management and Budget (OMB), may grant exceptions for classes of grants or recipients subject to the requirements of this part when exceptions are not prohibited by statute. However, in the interest of maximum uniformity, exceptions from the requirements of this part are permitted only in unusual circumstances. The Secretary may apply more restrictive requirements to a class of recipients when approved by OMB. The Secretary may apply less restrictive requirements when awarding small awards, except for those requirements on a case-by-case basis may also be made by the Secretary.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.5 Subawards.

Unless sections of this part specifically exclude subrecipients from coverage, the provisions of this part shall be applied to subrecipients performing work under awards if the subrecipients are institutions of higher education, hospitals, or other non-profit organizations. State and local government subrecipients are subject to the provisions of 34 CFR Part 80—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

Support B—Pre-Award Requirements

§ 74.10 Purpose.

Sections 74.11 through 74.17 prescribe forms and instructions and other pre-award matters to be used in applying for awards.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.11 Pre-award policies.

(a) *Use of Grants and Cooperative Agreements, and Contracts.* In each instance, the Secretary decides on the appropriate award instrument (i.e., grant, cooperative agreement, or contract). The Federal Grant and Cooperative Agreement Act (31 U.S.C. 6301-6306) governs the use of grants, cooperative agreements, and contracts. A grant or cooperative agreement shall be used only when the principal purpose of a transaction is to accomplish a public purpose of support or stimulation authorized by Federal statute. The statutory criterion for choosing between grants and cooperative agreements is that for the latter, substantial involvement is expected between ED and the recipient when carrying out the activity contemplated in the agreement. Contracts shall be used when the principal purpose is acquisition of property or services for the direct benefit or use of the Federal Government.

(b) *Public Notice and Priority Setting.* The Secretary notifies the public of intended funding priorities for discretionary grant programs through the Federal Register and other means. (29 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

The SPPOC for a particular State can be obtained from the Secretary or the *Catalog of Federal Domestic Assistance* (available from the Superintendent of Documents, Government Printing Office). The SPPOC shall advise the applicant whether the program for which application is made has been selected by that State for review.

(d) If ED does not use the SF-424 form, the Secretary may indicate whether the application is subject to review by the State under E.O. 12872.

As approved by the Office of Management and Budget under control number 1880-0513: (29 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110) (59 FR 34724, July 6, 1994, as amended at 60 FR 6660, Feb. 3, 1995)

§ 74.13 Debarment and suspension.

The Secretary and recipients shall comply with the nonprocurement debarment and suspension common rule (implemented by the Secretary in 34 CFR Part 85). This common rule restricts subawards and contracts with certain parties that are debarred, suspended, or otherwise excluded from or ineligible for participation in Federal procurement programs or activities.

§ 74.12 Forms for applying for Federal assistance.

(a) The Secretary complies with the applicable report clearance requirements of 5 CFR Part 1370—Controlling Paperwork Burdens on the Public—with regard to all forms used by ED in place of or as a supplement to the Standard Form 424 (SF-424) series.

(b) Applicants shall use the SF-424 series or those forms and instructions prescribed by the Secretary.

(c) For Federal programs covered by E.O. 12872—Intergovernmental Review of Federal Programs (implemented by the Secretary in 34 CFR Part 79—Intergovernmental Review of Department of Education Programs and Activities)—the applicant shall complete the appropriate sections of the SF-424 (Application for Federal Assistance) indicating whether the application was subject to review by the State. Single Point of Contact (SPPOC). The name and address

§ 74.14 Special award conditions.

(a) The Secretary may impose special award conditions. If an applicant or recipient—

- (1) Has a history of poor performance;
- (2) Is not financially stable;
- (3) Has a management system that does not meet the standards prescribed in this part;
- (4) Has not conformed to the terms and conditions of a previous award; or
- (5) Is not otherwise responsible.

(b) If special award conditions are established under paragraph (a) of this section, the Secretary notifies the applicant or recipient of—

- (1) The nature of the additional requirements;
- (2) The reason why the additional requirements are being imposed;
- (3) The nature of the corrective action needed;
- (4) The time allowed for completing the corrective actions; and

(5) The method for requesting reconsideration of the additional requirements imposed.

(c) Any special conditions are promptly removed once the conditions that prompted them have been corrected.

(29 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.15 Metric system of measurement.

The Metric Conversion Act, as amended by the Omnibus Trade and Competitiveness Act (15 U.S.C. 206) declares that the metric system is the preferred measurement system for U.S. trade and commerce. The Act requires each Federal agency to establish a date or dates in consultation with the Secretary of Commerce, when the metric system of measurement will be used in the agency's procurement, grants, and other business-related activities. Metric implementation may take longer where the use of the system is initially impractical or likely to cause significant hardships in the accomplishment of federally-funded activities. The Secretary follows the provisions of E.O. 12770—Metric Usage in Federal Government Programs.

(29 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.16 Resource Conservation and Recovery Act.

Under the Resource Conservation and Recovery Act (RCRA) (Pub. L. 94-580 codified at 42 U.S.C. 6962), any State agency or agency of a political subdivision of a State which is using appropriated Federal funds must comply with section 6002 of the RCRA. Section 6002 requires that preference be given in procurement programs to the purchase of specific products containing recycled materials identified in guidelines developed by the Environmental Protection Agency (EPA) (40 CFR Parts 247-254). Accordingly, recipients that receive direct Federal awards or other Federal funds shall give preference in their procurement programs funded with Federal funds to the purchase of recycled products pursuant to the EPA guidelines.

(29 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.17 Certifications and representations.

Unless prohibited by statute or contract regulation, the Secretary and recipients to submit certifications and representations required by statute or contract. If the recipient has a policy and continuing relationship with ED, Annual certifications and representations shall be signed by responsible officials with the authority to certify recipients' compliance with procurement requirements.

(29 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

Support C—Post-Award Requirements

FINANCIAL AND PROGRAM MANAGEMENT

§ 74.20 Purpose of financial and program management.

Sections 74.21 through 74.26 prescribe standards for financial management systems, methods for making awards and rules for—

- (a) Subawarding costs, sharing overhead requirements,
- (b) Accounting for program funds,
- (c) Approving budget revisions;
- (d) Making audits;
- (e) Determining allowability of costs and
- (f) Establishing fund availability.

(29 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.21 Standards for financial management systems.

(a) Recipients shall relate financial data to performance data and develop cost information whenever practical.

(b) Recipients' financial management systems shall provide for the following:

- (1) Accurate, current, and complete disclosure of the financial results of each federally-sponsored project in accordance with the reporting requirements established in § 74.52. If the award requires reporting on an accrual basis from a recipient that maintains records on other than an accrual basis, the recipient shall not be required to establish an accrual accounting system. These recipients may

Department of Health and Human Services, Department of Education, and the Department of the Interior, shall be of the same nature as the interest-bearing accounts established by the Secretary for each year on Federal cash balances or other accounts.

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected Federal and non-Federal cash resources.

(1) For those entities where CMIA and its implementing regulations do not apply, interest earned on Federal advances deposited in interest-bearing accounts shall be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to \$250 per year may be retained by the recipient for administrative expense. State universities and hospitals shall comply with CMIA, as it pertains to interest. If an entity subject to CMIA uses its own funds to pay pre-award costs for discretionary awards without prior written approval from the Secretary, it waives its right to recover the interest under CMIA.

(m) Except as noted elsewhere in this part, only the following forms are authorized for the recipients in requesting advances and reimbursements. The Secretary does not require more than an original and two copies of the following:

- (1) SF-270—Request for Advance or Reimbursement. The Secretary adopts the SF-270 as a standard form for all reimbursement requests.
- (2) SF-271—Outlay Report and Request for Reimbursement for Construction Programs. The Secretary adopts the SF-271 as the standard form to be used for requesting reimbursement for construction programs. However, the Secretary may substitute the SF-270 when the Secretary determines that it provides adequate information to meet Federal needs.

(20 U.S.C. 1221e-3(a)(1) and 347; OMB Circular A-110)

... shall be of the same nature as the interest-bearing accounts established by the Secretary for each year on Federal cash balances or other accounts.

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected Federal and non-Federal cash resources.

(1) For those entities where CMIA and its implementing regulations do not apply, interest earned on Federal advances deposited in interest-bearing accounts shall be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to \$250 per year may be retained by the recipient for administrative expense. State universities and hospitals shall comply with CMIA, as it pertains to interest. If an entity subject to CMIA uses its own funds to pay pre-award costs for discretionary awards without prior written approval from the Secretary, it waives its right to recover the interest under CMIA.

(m) Except as noted elsewhere in this part, only the following forms are authorized for the recipients in requesting advances and reimbursements. The Secretary does not require more than an original and two copies of the following:

- (1) SF-270—Request for Advance or Reimbursement. The Secretary adopts the SF-270 as a standard form for all reimbursement requests.
- (2) SF-271—Outlay Report and Request for Reimbursement for Construction Programs. The Secretary adopts the SF-271 as the standard form to be used for requesting reimbursement for construction programs. However, the Secretary may substitute the SF-270 when the Secretary determines that it provides adequate information to meet Federal needs.

(20 U.S.C. 1221e-3(a)(1) and 347; OMB Circular A-110)

... shall be of the same nature as the interest-bearing accounts established by the Secretary for each year on Federal cash balances or other accounts.

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected Federal and non-Federal cash resources.

(1) For those entities where CMIA and its implementing regulations do not apply, interest earned on Federal advances deposited in interest-bearing accounts shall be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to \$250 per year may be retained by the recipient for administrative expense. State universities and hospitals shall comply with CMIA, as it pertains to interest. If an entity subject to CMIA uses its own funds to pay pre-award costs for discretionary awards without prior written approval from the Secretary, it waives its right to recover the interest under CMIA.

(m) Except as noted elsewhere in this part, only the following forms are authorized for the recipients in requesting advances and reimbursements. The Secretary does not require more than an original and two copies of the following:

- (1) SF-270—Request for Advance or Reimbursement. The Secretary adopts the SF-270 as a standard form for all reimbursement requests.
- (2) SF-271—Outlay Report and Request for Reimbursement for Construction Programs. The Secretary adopts the SF-271 as the standard form to be used for requesting reimbursement for construction programs. However, the Secretary may substitute the SF-270 when the Secretary determines that it provides adequate information to meet Federal needs.

(20 U.S.C. 1221e-3(a)(1) and 347; OMB Circular A-110)

described in paragraph (b)(1) of this section, program income in excess of any limits shall be reported in the award program award report.

(d) The award program income is to be used, paragraph (b)(3) of this section applies automatically to all projects or programs except research. For awards that support research, paragraph (b)(1) of this section applies automatically unless the Secretary indicates in the terms and conditions another alternative on the award or the recipient is subject to special award conditions, as indicated in §74.14.

(e) Unless ED regulations or the terms and conditions of the award provide otherwise, recipients have no obligation to the Federal Government regarding program income earned after the end of the project period.

(f) If authorized by ED or the terms and conditions of the award, costs incidental to the generation of program income may be deducted from gross income to determine program income. Provided these costs have not been charged to the award.

(g) Proceeds from the sale of property shall be handled in accordance with the requirements of the Property Standards (See §§74.30 through 74.37).

(h) Unless ED regulations or the terms and conditions of the award provide otherwise, recipients have no obligation to the Federal Government with respect to program income earned from license fees and royalties for copyright, industrial, patent, trademark, and other intellectual property, and inventions produced under a grant or contract award and trademark arrangements (25 U.S.C. 18) apply to inventions made under an experimental, developmental, or research award.

(20 U.S.C. 1221e-3(a)(1) and 3024, OMB Circular A-110)

§74.25 Revision of budget and program plans.

(a) The budget plan is the financial expression of the project or program as approved during the award process. It may include either the Federal and non-Federal share, or only the Federal

share, depending upon ED requirements. It shall be revised to perform the project or program award purposes.

(b) The award program income shall be used, paragraph (b)(3) of this section applies automatically to all projects or programs except research. For awards that support research, paragraph (b)(1) of this section applies automatically unless the Secretary indicates in the terms and conditions another alternative on the award or the recipient is subject to special award conditions, as indicated in §74.14.

(1) Change in the scope or objective of the project or program (even if there is no associated budget revision requiring prior written approval).

(2) Change in a key person specified in the application or award document.

(3) The absence for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.

(4) The need for additional Federal funding.

(5) The transfer of amounts budgeted for indirect costs to absorb increases in direct costs, or vice versa. If approval is required by the Secretary:

(i) The inclusion, unless waived by the Secretary, of costs that require prior approval in accordance with OMB Circular A-21--Cost Principles for Institutions of Higher Education, OMB Circular A-122--Cost Principles for Non-Profit Organizations, or 45 CFR Part 74 Appendix B--Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals, or 48 CFR Part 31.101--Cost Principles and Procedures, as applicable.

(ii) The transfer of funds allotted for training advances direct payment for training) to other categories of expenses.

(8) Unless described in the application and funded in the approved award, the subaward, transfer or contracting out of any work under an award. This provision does not apply to the purchase of supplies, material, equipment, or general support services.

(d) No other prior approval requirements for specific items are imposed unless a deviation has been approved by OMB.

Office of the Secretary, Education

(e) Except for requirements listed in paragraphs (c)(1) and (c)(4) of this section, the Secretary may waive cost-sharing and administrative prior written approvals required by this part and OMB Circulars A-21 and A-122. These waivers may authorize recipients to do any one or more of the following:

(1) Incur pre-award costs 90 calendar days prior to award or more than 90 calendar days with the prior approval of the Secretary. All pre-award costs are incurred at the recipient's risk (i.e., the Secretary is under no obligation to reimburse these costs if for any reason the recipient does not receive an award or if the award is less than anticipated, and inadequate to cover these costs).

(2)(i) Initiate a one-time extension of the expiration date of the award of up to 12 months unless one or more of the following conditions apply:

(A) The terms and conditions of award prohibit the extension.

(B) The extension requires additional Federal funds.

(C) The extension involves any change in the approved objectives or scope of the project.

(i) For one-time extensions, the recipient shall notify the Secretary in writing with the supporting reasons and revised expiration date at least 10 days before the expiration date specified in the award. This one-time extension may not be exercised merely for the purpose of using unobligated balances.

(3) Carry forward unobligated balances to subsequent funding periods.

(4) For awards that support research, unless the Secretary provides otherwise in the award or in ED's regulations, the prior approval requirements described in paragraph (e) of this section are automatically waived (i.e., recipients need not obtain prior approval unless one of the conditions included in paragraph (e)(2)(1) of this section applies.

(5) The Secretary may restrict the transfer of funds among direct cost categories or programs, functions and activities for awards in which the Federal share of the project exceeds \$100,000 and the cumulative amount of the transfers exceeds or is expected to exceed 10 percent of the total budget as

initially approved by the Secretary. The Secretary does not permit a transfer of funds to be used for purposes not approved in the award or for other than the approved purposes.

(6) All other changes to nonconstruction awards, except for the changes described in paragraph (1) of this section, require prior approval.

(7) For construction awards, recipients shall request prior written approval promptly from the Secretary for budget revisions whenever—

(1) The revision results from change in the scope or the objective of the project or program;

(2) The need arises for additional Federal funds to complete the project or program;

(3) A revision is desired which involves specific costs for which prior written approval requirements may be imposed consistent with applicable OMB cost principles listed in §74.27.

(4) No other prior approval requirements for specific items may be imposed unless a deviation has been approved by OMB.

(8) When the Secretary makes an award that provides support for both construction and nonconstruction work, the Secretary may require the recipient to request prior approval from the Secretary before making any fund or budget transfers between the two types of work supported.

(9) For both construction and nonconstruction awards, recipients shall notify the Secretary in writing promptly whenever the amount of Federal authorized funds is expected to exceed the needs of the recipient for the project period by more than \$5,000 or five percent of the Federal award whichever is greater. This notification shall not be required if an application for additional funding is submitted for a continuation award.

(10) When requesting approval for budget revisions, recipients shall use the budget forms that were used in the application unless the Secretary indicates a letter of request suffices.

(11) Within 30 calendar days from the date of receipt of the request for budget revisions, the Secretary shall review the request and notify the recipient

whether the budget revisions have been approved. If the revision is still under consideration at the end of 30 calendar days, the Secretary informs the recipient in writing of the date when the recipient may expect the decision.

(Approved by the Office of Management and Enterprise Services on 12/15/94. 34 CFR 74.26 (20 U.S.C. 1221e-3(a)(1) and 3474) FR 6660, Feb. 3, 1995)

§ 74.28 Non-Federal audits.

(a) Recipients and subrecipients that are institutions of higher education or other non-profit organizations are subject to the audit requirements contained in OMB Circular A-133—Audits of Institutions of Higher Education and Other Non-Profit Institutions.

(b) State and local governments are subject to the audit requirements contained in the Single Audit Act (31 U.S.C. 7501-7) and the FD Regulations implementing OMB Circular A-128—

Private nonprofit organization other than (1) An institution of higher education; (2) a hospital; or (3) an organization named in OMB Circular A-122 as not subject to that circular.	OMB Circular A-122.
Educational institution.	OMB Circular A-271.
Hospital.	Appendix E in 45 CFR Part 74.
Commercial or for-profit organization other than a hospital and an educational institution.	48 CFR Part 41, General Cost Principles, and Prescribes or accounting standards that comply with cost principles applicable to ED.

(b) The cost principles applicable to a State, a local government, or Federally Recognized Indian tribal government are specified at 34 CFR § 80.22. (Authority: 20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.28 Period of availability of funds.

When a recipient receives a grant or contract award, the recipient must use the funds in accordance with the terms and conditions of the award. Allowable costs resulting from obligations incurred during the funding period and any pre-award costs authorized by the Secretary.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

Audits of State and Local Governments.

(c) Hospitals not covered by the audit provisions of OMB Circular A-133 are subject to the audit requirements established by the Secretary.

(d) Commercial organizations are subject to the audit requirements established by the Secretary of the primary awarding department. (20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.27 Allowable costs.

(a) For each kind of recipient, there is a set of cost principles for determining allowable costs. Allowability of costs are determined in accordance with the cost principles applicable to the entity incurring the costs, as specified in the following chart.

(NOTE: OMB circulars are available from the Office of Management and Budget, Publication Office, Room 2200, New Executive Office Building, Washington, DC 20503 (202) 395-7332.)

Use the principles in—

PROPERTY STANDARDS

§ 74.30 Purpose of property standards.

Sections 74.31 through 74.37 establish uniform standards governing management and disposition of property furnished by ED whose cost was charged to a Federal award. Recipients shall comply with these standards under awards from the Secretary, unless specifically required by Federal statute. The recipient may use its own property management standards and disposition provided it observes the provisions of §§ 74.31 through 74.37.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

Office of the Secretary, Education

§ 74.31 Insurance coverage.

Recipients shall, at a minimum, provide the equivalent insurance coverage for real property and equipment acquired with Federal funds as provided to property owned by the recipient. Federally-owned property need not be insured unless required by the awarding department. (20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.32 Real property.

The Secretary prescribes requirements for recipients concerning the use and disposition of real property acquired in whole or in part under awards. Unless otherwise provided by statute, the minimum requirements provide the following:

(a) Title to real property must vest in the recipient subject to the condition that the recipient shall use the real property for the authorized purpose of the project as long as it is needed and shall not encumber the property without approval of the Secretary.

(b) The recipient shall obtain written approval by the Secretary for the use of real property in other federally-sponsored projects when the recipient determines that the property is no longer needed for the purpose of the original project. Use in other projects shall be limited to those under federally-sponsored projects (i.e., awards) that have purposes consistent with those authorized for support by the Secretary.

(c) When the real property is no longer needed as provided in paragraphs (a) and (b) of this section, the recipient shall request disposition instructions from ED or its successor Federal awarding agency. The Secretary observes one or more of the following disposition instructions:

(1) The recipient may be permitted to retain title without further obligation to the Federal Government after it complies with the Federal Government for that percentage of the current fair market value of the property attributable to the Federal participation in the project.

(2) The recipient may be directed to sell the property under guidelines provided by the Secretary and pay the

Federal Government for that percentage of the current fair market value of the property attributable to the Federal participation in the project after deducting actual and reasonable selling and fix-up expenses, if any, from the proceeds, when the recipient determines that the recipient should, in the recipient's interest, sell the property to the extent practicable and result in the highest possible return.

(3) The recipient may be directed to transfer title to the property to the Federal Government or to an eligible third party. The recipient is entitled to compensation for its attributable percentage of the current fair market value of the property.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.33 Federally-owned and exempt property.

(a) Federally-owned property (1) Title to federally-owned property remains vested in the Federal Government. Recipients shall submit annually an inventory listing of federally-owned property in their custody to the Secretary. Upon completion of the award, when the property is no longer needed, the recipient shall report the property to the Secretary for further utilization.

(2) If ED has no further need for the property, it shall be declared excess and reported to the General Services Administration, unless the Secretary has statutory authority to dispose of the property by alternative method (e.g., the authority provided by the Federal Technology Transfer Act (16 U.S.C. 3710 (1)) to donate research and development to educational and non-profit organizations in accordance with the provisions of that Act. Methods of disposal shall be determined by the Secretary.

(b) Exempt property. When statutory authority exists, the Secretary may vest title to property acquired with Federal funds in the recipient without further obligation to the Federal Government and under conditions the Secretary considers appropriate. This property is "exempt property." Should

the Secretary not establish... title to exempt property upon... other obligation to the Federal Govern- ment.

§ 74.34 Equipment.

(a) Title to equipment acquired by a recipient with Federal funds shall vest in the recipient, subject to conditions of this section.

(c) The recipient shall use the equip- ment in the project or program for which it was acquired as long as need- ed, whether or not the project or pro- gram continues to be supported by Fed- eral funds and may not encumber the property without approval of the Sec- retary. When no longer needed for the original project or program, the recipi- ent shall use the equipment in connec- tion with its other federally-sponsored activities, in the following order of pri- ority:

- (1) Activities sponsored by the Fed- eral awarding agency which funded the original project and then
(2) Activities sponsored by other Fed- eral awarding agencies.

(d) During the time that equipment is used on the project or program for which it was acquired, the recipient shall make it available for use on other projects or programs if other use will not interfere with the work on the project or program for which the equip- ment was originally acquired. First preference for other use shall be given to other projects or programs spon- sored by the Federal awarding agency that funded the equipment. Second preference shall be given to other projects or programs sponsored by the Federal Government, use on other activities not sponsored by the Federal Government shall be per- missible if authorized by the Federal

When acquiring replacement equipment, the recipient may use the equipment and use the trade-in or proceeds to offset the costs of the replace- ment equipment subject to the ap- proval of the Secretary.

(c) The recipient's property manage- ment standards for equipment acquired with Federal funds and federally-owned equipment shall include all of the fol- lowing information:

- (1) A description of the equipment.
(2) Manufacturer's serial number, model number, Federal stock number, national stock number, or other identi- fication number.

(d) The source of the equipment shall include the award number.

(e) Information from which one can determine the percentage of Federal participation in the cost of the equip- ment (not applicable to equipment fur- nished by the Federal Government).

(f) Location and condition of the equipment and the date the informa- tion was reported.

(g) Ultimate disposition cost, including date of disposal and sales price or the method used to determine cur- rent fair market value where a recipi- ent compensates ED for its share.

(h) A physical inventory of equipment must be taken and the results rec- orded with the equipment records at least once every two years. Any dif- ferences between quantities deter- mined by the physical inspection and those shown in the accounting records shall be analyzed to determine the cause of the difference. The recipi- ent shall, in connection with the inven- tory, verify the existence, current uti- lization, and continued need for the equipment.

Office of the Secretary, Education

(4) A control system must be in effect to insure adequate safeguards to pre- vent loss, damage, or theft of the equipment. Any loss, damage, or theft of equipment shall be investigated and fully documented. If the equipment was owned by the Federal Government and the recipient shall promptly notify the Secretary.

(5) Adequate maintenance procedures must be implemented to keep the equipment in good condition.

(6) Where the recipient is authorized or required to sell the equipment, prop- erty sales procedures must be established which provide for competition to the extent practicable and result in the highest possible return.

(7) When the recipient no longer needs the equipment, the equipment may be used for other activities in ac- cordance with the following standards: (a) For equipment with a current per unit fair market value of \$5000 or more, the recipient may retain the equipment for other uses provided that compensa- tion is made to ED or its successor. The amount of compensation shall be computed by applying the percentage of Federal participation in the cost of the original project or program to the current fair market value of the equip- ment.

(8) If the recipient has no need for the equipment, the recipient shall request the Secretary's instructions from the Secretary. The Secretary shall determine whether the equipment can be used to meet ED requirements. If no require- ment exists within ED, the availability of the equipment shall be reported to the General Services Administration by the Secretary to determine whether a requirement for the equipment exists in other Federal agencies. The Sec- retary issues instructions to the recipi- ent no later than 120 calendar days after the recipient's request and the following procedures govern:

(a) If so instructed or if disposition instructions are not issued within 120 calendar days after the recipient's re- quest, the recipient shall sell the equipment and reimburse ED the amount computed by applying to the sales proceeds the percentage of Fed- eral participation in the cost of the original project or program. However, the recipient shall be permitted to de-

tain and retain from the Federal share an amount equal to the proceeds of the sale, net of the proceeds of the sale and handling expenses.

(b) If the recipient is instructed to ship the equipment elsewhere, the recipient is reimbursed by ED by the amount which is computed by applyin- the percentage of the recipient's par- ticipation in the cost of the original project or program to the current fair market value of the equipment, plus the reasonable shipping or handling costs incurred.

(c) If the recipient is instructed to dispose of the equipment, the recipient is reimbursed by ED for costs incurred in its disposition.

(d) The Secretary may reserve the right to transfer the title to the Fed- eral Government or to a third party of the equipment to the Federal Government or third party is otherwise eligi- ble under existing statutes. This trans- fer shall be subject to the following conditions: (1) The equipment must be appro- priately identified in the award or other document known to the recipient in writing.

The Secretary issues disposition instructions within 120 calendar days after receipt of a final inventory. The final inventory must list all equipment acquired with grant funds and federa- lly owned equipment. If the Secretary determines that issuer disposition instructions are not issued within the 120 calendar day period, the recipient shall apply the standards of this section as appropriate.

(2) Upon the Secretary exercises the right to take title, the equipment is subject to the provisions for federally- owned equipment.

(Approved by the Office of Management and Budget under control number 1890-013) (20 U.S.C. 1221e-3(a)(1) and 3474, OMB Cir- cular A-110)

(59 FR 34724, July 6, 1994, as amended at 60 FR 8226, Feb. 3, 1995)

(3) Supplies and other expendable personal property shall vest in the recipient upon acquisition. If there is a residual inventory of unused supplies exceeding \$5,000 in total aggregate value upon termination or completion

of the project or program, the recipient shall retain from the Federal share an amount equal to the proceeds of the sale, net of the proceeds of the sale and handling expenses. (11) If the recipient is instructed to ship the equipment elsewhere, the recipient is reimbursed by ED by the amount which is computed by applyin- the percentage of the recipient's par- ticipation in the cost of the original project or program to the current fair market value of the equipment, plus the reasonable shipping or handling costs incurred. (12) If the recipient is instructed to dispose of the equipment, the recipient is reimbursed by ED for costs incurred in its disposition. (13) The Secretary may reserve the right to transfer the title to the Fed- eral Government or to a third party of the equipment to the Federal Government or third party is otherwise eligi- ble under existing statutes. This trans- fer shall be subject to the following conditions: (1) The equipment must be appro- priately identified in the award or other document known to the recipient in writing. (14) The Secretary issues disposition instructions within 120 calendar days after receipt of a final inventory. The final inventory must list all equipment acquired with grant funds and federa- lly owned equipment. If the Secretary determines that issuer disposition instructions are not issued within the 120 calendar day period, the recipient shall apply the standards of this section as appropriate. (15) Upon the Secretary exercises the right to take title, the equipment is subject to the provisions for federally- owned equipment. (Approved by the Office of Management and Budget under control number 1890-013) (20 U.S.C. 1221e-3(a)(1) and 3474, OMB Cir- cular A-110) (59 FR 34724, July 6, 1994, as amended at 60 FR 8226, Feb. 3, 1995)

of the project or program and the supplies are not needed for any other federally-sponsored project or program, the recipient shall retain the supplies for use on non-Federal sponsored activities or sell them, but shall, in either case, compensate the Federal Government for its share. The amount of compensation shall be computed in the same manner as for equipment.

(b) The recipient may not use supplies acquired with Federal funds to provide services to non-Federal outside organizations for a fee that is less than private companies charge for similar services, unless specifically authorized by Federal law or as long as the recipient compensates the Federal Government for its share.

§ 74.36 Intangible property.

(a) The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award, ED and any other Federal awarding agency reserve a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

(b) Recipients are subject to applicable regulations governing patents and inventions, including Government-wide regulations issued by the Department of Commerce at 37 CFR Part 401-- Rights to Inventions Made by Non-Profit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements.

(c) Unless waived by the Secretary, the Federal Government has the right to--

- (1) Obtain, reproduce, publish, or otherwise use the data first produced under an award; and
- (2) Authorize others to receive, reproduce, publish, or otherwise use these data for Federal purposes.

(b) Title to intangible property and data instruments acquired under an award or subaward vests upon acquisition in the recipient. The recipient shall use data produced under the award for authorized purposes and the recipient shall not release the pro-

erty without approval of the Secretary. When no longer needed for the originally authorized purpose, disposition of the intangible property shall occur in accordance with the provisions of § 74.36(g).

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.37 Property trust relationship.

Real property, equipment, intangible property, and debt instruments that are acquired or improved with Federal funds must be held in trust by the recipient as trustee for the beneficiaries of the project or program under which the property was acquired or improved. The recipient may require recipients of the award or other government property to hold property that pertains to the project or program in trust for or improved with Federal funds and then use and disposition conditions apply to the property.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

PROCUREMENT STANDARDS

§ 74.40 Purpose of procurement standards.

Sections 74.41 through 74.48 contain standards for use by recipients in establishing procedures for the procurement of supplies and other expendable property, equipment, real property, and other services with Federal funds. These standards are designed to ensure that these materials and services are obtained in an effective manner and in compliance with the provisions of applicable Federal statutes and executive orders. The Secretary does not impose additional procurement standards or requirements upon recipients, unless specifically required by Federal statute or executive order or as authorized in § 74.4 or § 74.14.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.41 Recipient responsibilities.

The standards contained in this section do not relieve the recipient of the contractual responsibilities arising under its contract. The recipient is the responsible authority accepting the award to the Secretary, accepting the

statement and satisfaction of all contractual and administrative issues arising out of procurements entered into in support of an award or other agreement. This includes disputes, claims, protests of award, source evaluation, or other matters of a contractual nature. Matters concerning violation of statute are to be referred to Federal, State or local authority that may have proper jurisdiction.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.42 Codes of conduct.

The recipient shall maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts. No employee, officer, or agent shall participate in the selection award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved. A conflict would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for an award. The officer, employees, and agents of the recipient shall neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or parties to subagreements. However, recipients may set standards for situations in which the financial interest is not substantial, or the gift is an unsolicited item of nominal value. The standards of conduct shall provide for disciplinary actions to be applied for violations of these standards by officers, employees, or agents of the recipient.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.43 Competition.

All procurement transactions shall be conducted in a manner to provide to the maximum extent practical, open and free competition. The recipient shall be alert to organizational conflicts of interest as well as noncompetitive practices among contractors that may result or eliminate competition or otherwise restrain trade. In order to

ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft specifications, requirements, statements of work, invitations for bids or requests for proposals shall be excluded from competing for procurements. Awards must be made to the bidder or offeror whose bid or offer is responsive to the solicitation and is most advantageous to the recipient.

price, quality and other factors considered. Solicitations shall clearly establish all requirements that the bidder or offeror shall fulfill in order for the bid or offer to be evaluated by the recipient. Any and all bids or offers may be rejected and opened if in the recipient's interest.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

(a) All recipients shall establish written procurement procedures. These procedures must provide for, at a minimum, that:

- (1) Recipients avoid purchasing unnecessary items;
- (2) Where appropriate, an analysis is made of lease and purchase alternatives to determine which would be the most economical and practical procurement for the Federal Government;
- (3) The solicitations for goods and services provide for all of the following:
 - (i) A clear and accurate description of the technical requirements for the material, product, or service to be procured. In competitive procurements, a description shall not contain features which unduly restrict competition.
 - (ii) Requirements which the bidder/officer must fulfill and all other factors to be used in evaluating bids or proposals.
- (4) A description, whenever practicable, of technical requirements in terms of functions to be performed or performance required, including the range of acceptable characteristics or minimum acceptable standards.
- (5) The specific features of brand names or equal descriptions that bidders are required to meet when these items are included in the solicitation.

The recipient shall accept the award to the Secretary and commercially feasible,

18

19

of products and services, and the metric system of measurement.

(V) Preference, to the extent practicable and economically feasible, for products and services that conserve natural resources and protect the environment, and are energy efficient.

(D) Positive efforts shall be made by recipients to utilize small businesses, minority-owned firms, and women's business enterprises, whenever possible. Recipients of Federal awards shall take all of the following steps to further this goal:

- (1) Ensure that small businesses, minority-owned firms, and women's business enterprises are used to the fullest extent practicable.
- (2) Make information on forthcoming opportunities available and arrange for pre-bids for purchases and contracts to be encouraged and facilitate participation by small businesses, minority-owned firms, and women's business enterprises.

(4) Encourage contracting with corporations of small businesses, minority-owned firms and women's business enterprises when a contract is too large for one of these firms to handle individually.

(5) Use the services and assistance, as appropriate, of organizations such as the Small Business Administration and the Department of Commerce's Minority Business Development Agency in the solicitation and utilization of small businesses, minority-owned firms and women's business enterprises.

(6) The type of procuring instruments used (e.g., fixed price contracts, cost reimbursable contracts, purchase orders, and incentive contracts) shall be determined by the recipient but must be appropriate for the particular procurement and for promoting the best interests of the program or project involved. The "cost-plus-a-percentage-of-cost" or "percentage of construction cost" methods of contracting must not be used.

(d) Contracts are made only with responsible contractors who possess the

ability to perform successfully under the terms and conditions of the proposed procurement. Consideration is given to matters as contractor integrity; record of past performance; financial and technical resources or accessibility to other necessary resources. In certain circumstances, contracts with certain parties are restricted by E.O. 12549 (implemented by E.O. 12889—Department and Suspension of Recipients) shall, on request, make available for the Secretary, pre-award review and procurement documents, such as request for proposals or invitation for bids, independent cost estimates, etc., when any of the following conditions apply:

- (1) A recipient's procurement process or operation fails to comply with the procurement standards in this part.
- (2) The procurement is expected to exceed the threshold for the threshold.
- (3) The proposed contract over the small purchase threshold is to be awarded to other than the apparent low bidder under a sealed bid procurement.

(3) A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount of the small purchase threshold.

(Approved by the Office of Management and Budget under control number 1880-0513) (20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110) (50 FR 34724, July 6, 1994, as amended at 60 FR 6660, Feb. 3, 1995)

§ 74.45 Cost and price analysis.

Some form of cost or price analysis must be made and documented in the procurement files in connection with every procurement action. Price analysis may be accomplished in various ways, including the comparison of prices and similar data, together with discounts. Cost analysis is the re-

view and evaluation of each element of cost to determine reasonableness, allocability, and allowability.

(Approved by the Office of Management and Budget under control number 1880-0513) (20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110) (50 FR 34724, July 6, 1994, as amended at 60 FR 6660, Feb. 3, 1995)

§ 74.46 Procurement records.

Procurement records and files for purchases in excess of the small purchase threshold must include the following at a minimum—

- (a) Basis for contractor selection.
- (b) Justification for lack of competition when competitive bids or offers are not obtained.
- (c) Basis for award cost or price.

(Approved by the Office of Management and Budget under control number 1880-0513) (20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110) (50 FR 34724, July 6, 1994, as amended at 60 FR 6660, Feb. 3, 1995)

§ 74.47 Contract administration.

A system for contract administration must be maintained to ensure conformance with the terms, conditions and specifications of the contract and to ensure adequate and timely follow up of all purchases. Recipients shall evaluate contractor performance and document, as appropriate, whether contractors have met the terms, conditions, and specifications of the contract.

(Approved by the Office of Management and Budget under control number 1880-0513) (20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110) (50 FR 34724, July 6, 1994, as amended at 60 FR 6660, Feb. 3, 1995)

§ 74.48 Contract provisions.

The recipient shall include, in addition to provisions to define a sound and complete agreement, the following provisions in all contracts. The following provisions must also be applied to subcontracts:

- (a) Contracts in excess of the small purchase threshold shall contain contractual provisions or conditions that allow for administrative, contractual, or legal remedies in instances in which

(1) A contractor violates or breaches the contract terms, and provide for remedies as may be appropriate.

All contracts in excess of the small purchase threshold shall contain suitable provisions for termination which termination shall be effective on the date of settlement. In addition, contracts must describe conditions under which the contract may be terminated for default, as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor.

Except as otherwise required by statute, an award that requires subcontracting (or facility improvement) must provide for the recipient to follow its own requirements relating to bid or award, performance bonds, and payment bonds unless the construction contract is for the purchase of a service.

(2) A bid guarantee from each bidder equivalent to five percent of the bid price. The "bid guarantee" must consist of a firm commitment such as a bid bond, certified check, or other negotiable instrument, accompanying a bid as assurance that the bidder shall meet the requirements of the contract documents as may be required within the time specified.

(3) A performance bond on the part of the contractor for 100 percent of the contract price. A "performance bond" is one executed in connection with a contract to secure fulfillment of all the contractor's obligations under a contract.

(4) A payment bond on the part of the contractor for 100 percent of the contract price. A "payment bond" is one executed in connection with a contract to assure payment as required by statute of all persons supplying labor and material in the execution of the work provided for in the contract.

(b) The Secretary may, at any time, require the recipient to submit to the Secretary for review and approval any records, reports, or other documents which the recipient has prepared or caused to be prepared in connection with the award, including but not limited to the following:

- (1) The Secretary may require the recipient to submit to the Secretary for review and approval any records, reports, or other documents which the recipient has prepared or caused to be prepared in connection with the award, including but not limited to the following:
- (2) The Secretary may require the recipient to submit to the Secretary for review and approval any records, reports, or other documents which the recipient has prepared or caused to be prepared in connection with the award, including but not limited to the following:

(Approved by the Office of Management and Budget under control number 1890-0513) (20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110) (59 FR 3474, July 6, 1994, as amended at 66 FR 6680, Feb. 3, 1995)

§ 74.53 Retention and access requirements for records.

(a) This section establishes requirements for records for awards to recipients. The Secretary does not impose any other record retention or access requirements upon recipients.

(b) Financial records supporting documents, statistical records, and all other records pertaining to an award shall be retained for a period of 3 years after final disposition of the award.

(c) From the date of the submission of the quarterly or annual financial report, as authorized by the Secretary. The only exceptions are the following:

- (1) If any litigation claim or audit is started before the expiration of the 3 year period, the records shall be retained until all litigation claims are finally disposed of, and the records shall be retained until the records have been resolved and final action taken.
- (2) Records for cost proposals and equipment acquired with Federal funds shall be retained for 3 years after final disposition.
- (3) When records are transferred to or maintained by the Secretary, the 3 year retention requirement is not applicable to the recipient.
- (4) Indirect cost rate proposals, cost allocations plans, etc. as specified in § 74.83(g).

(c) Copies of original records may be substituted for the original records if authorized by the Secretary.

to the Secretary or the subrecipient is not required to submit to the recipient the proposal, plan, or other computation for negotiation purposes, then the 5-year retention period for the proposal, plan, or other computation and its supporting records starts at the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

(Approved by the Office of Management and Budget under control number 1890-0513) (20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110) (59 FR 3474, July 6, 1994, as amended at 66 FR 6680, Feb. 3, 1995)

TERMINATION AND ENFORCEMENT

§ 74.60 Purpose of termination and enforcement.

Sections 74.61 and 74.62 establish uniform suspension, termination, and enforcement procedures.

(20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110)

§ 74.61 Termination.

(a) Awards may be terminated in whole or in part only—

- (1) If the Secretary, if a recipient materially fails to comply with the terms and conditions of an award;
- (2) By the Secretary with the consent of the recipient in which case the two parties shall agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated.

(b) By the recipient, upon sending to the Secretary written notification containing the reasons for the termination of the effective date, and in the case of partial termination, the portion to be terminated. However, if the Secretary determines in the case of partial termination that the reduced or modified portion of the grant will not accomplish the purposes for which the grant was made, it may terminate the grant in its entirety under either paragraphs (a)(1) or (2) of this section.

(c) If costs are allowed under an award, the responsibilities of the recipient referred to in § 74.71(a), including those for property management as applicable, shall be considered in the termination of the award, and provision

shall be made for continuing responsibility for the portion of the award terminated. The recipient shall be responsible for the portion of the award terminated.

(Approved by the Office of Management and Budget under control number 1890-0513) (20 U.S.C. 1221e-3(a)(1) and 3474; OMB Circular A-110) (59 FR 3474, July 6, 1994, as amended at 66 FR 6680, Feb. 3, 1995)

§ 74.62 Enforcement.

(a) If a recipient fails to comply with the terms and conditions of an award, which is stated in a Federal statute, regulation, or assurance, application, or other agreement, the Secretary may, in addition to imposing any of the special conditions outlined in § 74.14, take one or more of the following actions, as appropriate in the circumstances:

- (1) Temporarily withhold cash payments pending correction of the delinquency by the recipient or more severe enforcement action by the Secretary.
- (2) Rescind (that is, deny both use of funds and any applicable matching credit for all or part of the cost of the activity or action not in compliance).
- (3) Wholly or partly suspend or terminate the current award.
- (4) Withhold further awards for the present award year.

(b) In addition, the Secretary provides the recipient an opportunity for hearing, appeal, or other administrative proceeding to which the recipient is entitled under any statute or regulation applicable to the action involved.

(c) Effects of suspension and termination. (1) If a recipient is suspended or terminated, the Secretary may, at the discretion of the Secretary, suspend or terminate the award or portion of the award which are necessary and not otherwise available are allowable.

(2) The costs would be allowable if the award were not suspended or expired prematurely at the end of the funding period.

75.105 Annual priorities.

APPLICATION COMMENTS

75.109 Changes to application; number of copies.

75.112 Include a proposed project period and a timeline.

75.117 Information needed for a multi-year project.

75.118 Requirements for a continuation award.

75.119 Information needed if private school students participate.

SEPARATE APPLICATIONS--ALTERNATIVE PROGRAMS

75.125 Submit a separate application to each program, except under the Joint Funding Simplification Act.

75.126 Application must list all programs to which it is submitted.

GROUP APPLICATIONS

75.127 Eligible parties may apply as a group.

75.128 Who acts as applicant; the group agreement.

STATE COMMENT PROCEDURES

75.136 Review procedure if State may comment on applications; purpose of §§75.136-75.138.

75.137 When an applicant under §75.136 must submit a comment to the State; procedure for comment.

75.138 When an applicant under §75.136 must submit a comment to the State; procedure for comment.

75.139 When an applicant under §75.136 must submit a comment to the State; procedure for comment.

DEVELOPMENT OF CURRICULAR INSTRUMENTAL MATERIALS

75.190 Consultation.

75.191 Consultation costs.

75.192 Dissemination.

SUBPART D--How Grants Are Made

75.200 How applications for new grants and cooperative agreements are selected for funding; standards for use of cooperative agreements.

75.201 How to use the selection criteria.

SELECTION PROCEDURES

75.215 How the Department selects a new project; purpose of §§75.215-75.222.

75.216 Applications not evaluated for funding.

75.217 How the Secretary selects applications for new grants.

75.218 Applications not evaluated or selected for funding.

75.219 Exceptions to the procedures under §75.217.

75.220 Procedure; the Department uses under §75.219(a).

75.221 Procedure; the Department uses under §75.219(b).

75.222 Procedure; the Department uses under §75.219(c).

75.230 How the Department makes a grant; purpose of §§75.230-75.238.

75.231 Additional information.

75.232 The cost calculator; basis for grant amount.

75.233 Setting the amount of the grant.

75.234 The conditions of the grant.

75.235 The notification of grant award.

75.236 Effect of the grant.

75.237 Approval of Multi-Year Projects

75.238 Project period can be up to 60 months.

75.239 The budget period.

75.240 Continuation of a multi-year project after the first budget period.

75.241 [Reserved]

75.242 Miscellaneous

75.260 Allowments and reallocations.

75.261 Extension of a project period.

75.262 Conversion of a grant or a cooperative agreement.

75.263 [Reserved]

75.264 [Reserved]

75.265 [Reserved]

75.266 [Reserved]

75.267 [Reserved]

75.268 [Reserved]

75.269 [Reserved]

75.270 [Reserved]

75.271 [Reserved]

75.272 [Reserved]

75.273 [Reserved]

ALLOWABLE COSTS

75.590 General cost principles.

75.591 Limits on final costs of a project.

75.592 Use of funds for religion prohibited.

75.593 Acquisition of real property; construction.

75.594 Training grants--automatic increases for non-Federal dependents.

75.595 [Reserved]

75.596 [Reserved]

75.597 [Reserved]

75.598 [Reserved]

75.599 [Reserved]

75.600 [Reserved]

75.601 [Reserved]

75.602 [Reserved]

75.603 [Reserved]

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75.616 [Reserved]

75.617 [Reserved]

75.618 [Reserved]

75.619 [Reserved]

75.620 [Reserved]

75.621 [Reserved]

75.622 [Reserved]

75.623 [Reserved]

Appendix D - 34 CFR Part 97--Protection of Human Subjects, Final Rule

Wednesday
November 26, 1997

Federal Register

Part II

**Department of
Education**

34 CFR Part 97
Protection of Human Subjects; Final Rule

DEPARTMENT OF EDUCATION

34 CFR Part 97

RIN 1880-AA75

Protection of Human Subjects

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the Department's regulations governing the protection of human research subjects to add special protections for children who are involved as subjects of research. These amendments to the Department's regulations are needed to secure additional protections for children who are involved as subjects of research. The regulations will, for research involving children as subjects, remove exemptions for certain kinds of research, modify the informed consent provisions, and further limit the risks to which children may be made vulnerable. These amendments will make the Department's policy regarding the protection of children as research subjects consistent with the regulations of the Department of Health and Human Services and the Federal Policy for the Protection of Children as practiced by other research agencies of the Federal government.

EFFECTIVE DATE: These regulations take effect December 26, 1997.

FOR FURTHER INFORMATION CONTACT: Kent H. Hannaman, U.S. Department of Education, 600 Independence Avenue, SW., Room 5624, Regional Office Building 3, Washington, D.C. 20202-4651. Telephone: (202) 708-5207. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

SUPPLEMENTARY INFORMATION: The Secretary adopts for the Department of Education regulations that are already in effect for research supported or conducted by the Department of Health and Human Services (DHHS), Subpart D—Additional DHHS Protections for Children Involved as Subjects in Research (Subpart D). These regulations contain provisions specifically designed to protect children who are involved in research as subjects. Children are involved as subjects of important research that will benefit the Nation's

children. Balancing the importance of this research with the needs of children, the Secretary is adding these protections because the research activities supported by the Department often include children, and the Department has a particular interest in protecting the welfare of children.

The Common Rule, in which the Department of Education is a participant, currently only includes Subpart A of the DHHS rule. To ensure that the protections in Subpart D apply to research subjects who are children, the Secretary adopts Subpart D, applying it to research programs of the Department.

On May 22, 1997, the Secretary proposed to add Subpart D through a notice of proposed rulemaking (NPRM) published in the *Federal Register* (62 FR 28156-28159). In the preamble to that NPRM, the Secretary discussed the current government-wide and Department of Education policy, the additional protections provided by these regulations, the additional costs and administrative burdens, alternative policy mechanisms, and additional protections for children as education research subjects other than the protections in these regulations.

There are no differences between the proposed regulations and these final regulations.

Analysis of Public Comment

In response to the Secretary's invitation in the NPRM, three parties submitted comments on the proposed regulations. Two commenters were from associations representing affected communities, and one commenter was an individual at an institution of higher education. Two of the commenters expressed support for the protections and the consistency of these protections with policies of other Federal agencies. An analysis of the other comments follow.

Comment: One commenter expressed concern over whether the regulations were sufficiently clear about the need to provide potential research subjects with specific information about their involvement in proposed research activities.

Discussion: The Secretary agrees that potential research subjects must have appropriate information about a specific research activity in order to give informed consent to participate. Subpart A of the existing regulations protecting human research subjects requires, as part of the provisions concerning informed consent, that potential research subjects be given information including the purpose of the particular research activity, the specific

procedures to be followed, and the risks and benefits to the subject. Because existing regulations cover this subject, Subpart D, as proposed in the NPRM, has not been changed.

Changes: None.

Comment: One commenter recommended that the regulations include guidance stating that research project descriptions include information about what safeguards will be put into place in order to respond to anticipated risks that actually occur.

Discussion: Information about safeguards for anticipated risks in research is important both for the review and approval of research activities and for the informed consent of potential research subjects. Subpart A of the existing regulations for the protection of human research subjects calls for information about available medical treatment in cases of injury as part of the informed consent process for research involving more than minimal risks. This information should be made available to any potential human research subject, not just children who are potential research subjects. Because existing regulations cover this subject, Subpart D, as proposed in the NPRM, has not been changed.

Changes: None.

Paperwork Reduction Act of 1995

These final regulations have been examined under the Paperwork Reduction Act of 1995 and have been found to contain no additional information collection requirements.

Assessment of Educational Impact

In the NPRM the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the NPRM and on its own review, the Department 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.

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Note: The official version of this document is the document published in the Federal Register.

List of Subjects in 34 CFR Part 97

Human subjects, Reporting and recordkeeping requirements, Research. (Catalog of Federal Domestic Assistance Number does not apply)

Dated: November 18, 1997.

Richard W. Riley,
Secretary of Education.

The Secretary amends Part 97 of Title 34 of the Code of Federal Regulations as follows:

PART 97—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for Part 97 is revised to read as follows:

Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; 42 U.S.C. 300v-1(b).

2. Sections 97.101 through 97.124 are designated as Subpart A—Federal Policy for the Protection of Human Subjects (Basic ED Policy for Protection of Human Research Subjects) and Subparts B and C are reserved.

3. Sections 97.101, 97.102, 97.103, and 97.107 through 97.124 are amended by adding authority citations to read as follows:

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

4. A new Subpart D containing §§ 97.401 through 97.409 is added to read as follows:

Subpart D—Additional ED Protections for Children Who are Subjects in Research

97.401 To what do these regulations apply?

97.402 Definitions.

97.403 IRB duties.

97.404 Research not involving greater than minimal risk.

97.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

97.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

97.407 Research not otherwise approvable which presents an opportunity to

understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

97.408 Requirements for permission by parents or guardians and for assent by children.

97.409 Wards.

Subpart D—Additional ED Protections for Children Who are Subjects in Research

§ 97.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects conducted or supported by the Department of Education.

(1) This subpart applies to research conducted by Department employees.

(2) This subpart applies to research conducted or supported by the Department of Education outside the United States, but in appropriate circumstances the Secretary may, under § 97.101(i), waive the applicability of some or all of the requirements of the regulations in this subpart for that research.

(b) Exemptions in § 97.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption in § 97.101(b)(2) regarding educational tests is also applicable to this subpart. The exemption in § 97.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator or investigators do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in § 97.101(c) through (i) are applicable to this subpart.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

§ 97.402 Definitions.

The definitions in § 97.102 apply to this subpart. In addition, the following definitions also apply to this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

§ 97.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

§ 97.404 Research not involving greater than minimal risk.

ED conducts or funds research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

§ 97.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

ED conducts or funds research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that—

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

§ 97.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

ED conducts or funds research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not

likely to contribute to the well-being of the subject, only if the IRB finds that—

- (a) The risk represents a minor increase over minimal risk;
- (b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- (c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- (d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

§ 97.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

ED conducts or funds research that the IRB does not believe meets the requirements of § 97.404, § 97.405, or § 97.406 only if—

- (a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- (b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either that—
 - (1) The research in fact satisfies the conditions of § 97.404, § 97.405, or § 97.406, as applicable; or
 - (2)(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - (ii) The research will be conducted in accordance with sound ethical principles; and
 - (iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

§ 97.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, if in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even if the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 97.116.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 97.116, that adequate provisions are made for soliciting the permission of each child's parent(s) or guardian(s). If parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 97.404 or § 97.405. If research is covered by §§ 97.406 and 97.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or if only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 97.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children),

it may waive the consent requirements in subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians must be documented in accordance with and to the extent required by § 97.117.

(e) If the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

§ 97.409 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity may be included in research approved under § 97.406 or § 97.407 only if that research is—

- (1) Related to their status as wards; or
- (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or *in loco parentis*. One individual may serve as advocate for more than one child. The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator or investigators, or the guardian organization.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

[FR Doc. 97-31020 Filed 11-25-97; 8:45 am] BILLING CODE 4000-01-P

PART 97—PROTECTION OF HUMAN SUBJECTS

written notice sent within 15 days of the Secretary's receipt of the ALJ's decision.

(c)(1) Either party may request review by the Secretary by submitting a brief or written materials to the Secretary within 20 days of the party's receipt of the ALJ's decision. The submission must explain why the decision of the ALJ should be modified, reversed, or remanded. The other party shall respond within 20 days of receipt of the brief or written materials filed by the opposing party.

(2) Neither party may introduce new evidence on review.

(d) The decision of the ALJ ordering the repayment of Federal financial assistance or terminating the eligibility of an IHE, SEA, or IEA does not take effect pending the Secretary's review.

(e)(1) The Secretary reviews the ALJ's decision considering only evidence introduced into the record.

(2) The Secretary's decision may affirm, modify, reverse or remand the ALJ's decision and includes a statement of reasons for the decision.

(Authority: 20 U.S.C. 1145g, 3224a)

§ 86.411 What are the procedures for requesting reinstatement of eligibility?

(a)(1) An IHE, SEA, or IEA whose eligibility to receive any or all forms of Federal financial assistance has been terminated may file with the Department a request for reinstatement as an eligible entity no earlier than 18 months after the effective date of the termination.

(2) In order to be reinstated, the IHE, SEA, or IEA must demonstrate that it has corrected the violation or violations on which the termination was based, and that it has met any repayment obligation imposed upon it under § 86.301(b)(1) of this part.

(b) In addition to the requirements of paragraph (a) of this section, the IHE, SEA, or IEA shall comply with the requirements and procedures for reinstatement of eligibility applicable to any Federal program under which it desires to receive Federal financial assistance.

(Authority: 20 U.S.C. 1145g, 3224a)

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—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. 300a-1(b), Source: 56 FR 28012, 28021, June 18, 1991, unless otherwise noted.

§ 97.101 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 § 97.102(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 § 97.102(e) must be reviewed and approved, in compliance with § 97.101, 97.102, and § 97.107 through 97.117 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:

(1) 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 person-

ally 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:

(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 provided for in this policy. 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 on the Ethical Principles of Human Rights issued in 1964 by the General Assembly of the United Nations, 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 requirements 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 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

June 20, 1991

§ 97.102 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, investigations 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

that 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 observations of public behavior when the investigator(s) do not participate in the activities being observed.

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 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 activ-

ity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§ 97.103 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 that is emptied or waived under §97.101 (b) or (1).

(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; representation; capacity; indications of experience such as board certifications, Honors, etc., sufficient to describe each member's chief unimpacted 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 accordance with §97.103(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 (1) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (1) 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 (1) 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 (1) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this

policy or the requirements of determinations of the IRB and (1) 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 §97.101 (b) or (1). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §97.103 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 §97.103 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)
[56 FR 29012, 29021, June 18, 1991; 56 FR 29756, June 28, 1991]

§97.104—97.106 [Reserved]

§97.107 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 non-scientific 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.

§ 97.108 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 §97.103(b)(4) and, to the extent required by, §97.103(b)(5).

(b) Except when an expedited review procedure is used (see §97.110), 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 non-scientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 97.109 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 §97.116. The IRB may require that information, in addition to that specifically mentioned in §97.116, be given to the subjects when in the IRB's judgment the information would meaning-

fully 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 § 97.117.

(d) ~~When~~ 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)

§ 97.110 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 § 97.108(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.

§ 97.111 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

Office of the Secretary, Education

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 § 97.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 97.117.

(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.

§ 97.112 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.

§ 97.113 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)

§ 97.114 Cooperative research.

Cooperative research projects at whose 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.

§ 97.115 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 § 97.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in § 97.103(b)(4) and § 97.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § 97.116(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)

§97.116 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 consist 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 practically 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 practically 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)

§97.117 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 §97.116. 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 §97.116 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 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 95995-00020)

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

Certain types of applications for grants, cooperative arrangements, or other types of submitting arrangements with 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 §97.101 (b) or (d), 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.

§97.119 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.

§97.120 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.

§97.121 (Reserved)

§97.122 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.

§97.123 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 paragraph (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 had, 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).

§97.124 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.

PART 98—STUDENT RIGHTS IN RESEARCH, EXPERIMENTAL PROGRAMS, AND TESTING

- Sec. 98.1 Applicability of part.
- 98.2 Definitions.
- 98.3 Access to instructional material used in a research or experimentation program.
- 98.4
- 98.5 Protection of students' privacy in examination, testing, or treatment.
- 98.6 Information and investigation office.
- 98.7 Reports.
- 98.7 Filing a complaint.
- 98.8 Notice of the complaint.
- 98.9 Investigation and findings.
- 98.10 Enforcement of the findings.

AUTHORITY: Sec. 514(a) of Pub. L. 93-380, 88 Stat. 674 (20 U.S.C. 1232h(e)); sec. 1250 of Pub. L. 95-561, 92 Stat. 2355-2356 (20 U.S.C. 1232h(b)); and sec. 408(e)(1) of Pub. L. 90-247, 86 Stat. 559-560, as amended (20 U.S.C. 1221e-4(a)(1)); sec. 414(a) of Pub. L. 95-48, 89 Stat. 655 (20 U.S.C. 3474(e)), unless otherwise noted.

SOURCE: 49 FR 33321, Sept. 6, 1984, unless otherwise noted.

§98.1 Applicability of part.

This part applies to any program administered by the Secretary of Education that:

(1) (a)(1) Was transferred to the Department by the Department of Education Organization Act (DEOA); and

(2) Was administered by the Education Division of the Department of Health, Education, and Welfare on the day before the effective date of the DEOA, or

(b) Was enacted after the effective date of the DEOA, unless the law enacting the new Federal program has the effect of making section 439 of the General Education Provisions Act inapplicable.

(c) The following chart lists the funded programs to which part 98 does not apply as of February 16, 1984.

Name of program	Authorizing statute	Implementing regulation
1. High School Equivalency Program and College Assistance Migrant Program	Section 418A of the Higher Education Act of 1965 as amended by the Education Amendments of 1980 (Pub. L. 96-574) 20 U.S.C. 1070a-21	part 206
2. Programs administered by the Commissioner of the Rehabilitation Services Administration.	The Rehabilitation Act of 1973 as amended by Pub. L. 95-502 (29 U.S.C. 700, et seq.).	parts 351-356, 361, 362, 365, 366, 368-375, 378, 379, 385-390, and 395.
3. College Housing	Title IV of the Housing Act of 1950 as amended (12 U.S.C. 1749, et seq.).	part 614.

(Authority: 20 U.S.C. 1221e-3(a)(1), 1230, 1232h, 3487, 3507)

§98.2 Definitions.

(a) The following terms used in this part are defined in 34 CFR part 77: "Department," "Recipient," "Secretary."

(b) The following definitions apply to this part: Act means the General Education Provisions Act.

Office means the information and investigation office specified in §98.5. (Authority: 20 U.S.C. 1221e-3(a)(1))

§98.3 Access to instructional material used in a research or experimentation program.

(a) All instructional material—including teachers' manuals, films, tapes, or other supplementary instructional material—which will be used in connection with any research or experimentation program or project shall be available for inspection by the parents or guardians of the children engaged in such program or project.

(b) For the purpose of this part research or experimentation program or project means any program or project