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## **DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**

**Public Health Service**

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### **NATIONAL RESEARCH SERVICE AWARDS**

**Proposed Rules**

## PROPOSED RULES

DEPARTMENT OF HEALTH,  
EDUCATION, AND WELFAREPublic Health Service  
[ 42 CFR Part 66 ]

## NATIONAL RESEARCH SERVICE AWARDS

## Notice of Proposed Rulemaking

Section 472(a)(1)(A) of the Public Health Service Act, as added by the National Research Service Award Act of 1974 (Title I, Pub. L. 93-348), directed the Secretary of Health, Education, and Welfare to provide National Research Service Awards for (1) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration in matters relating to the cause, diagnosis, prevention, and treatment of the disease (or diseases) or other health problems to which the activities of NIH and ADAMHA are directed, (2) training at NIH and ADAMHA of individuals to undertake such research, (3) biomedical and behavioral research at non-Federal public and nonprofit private institutions, and (4) predoctoral and postdoctoral training at such institutions of individuals to undertake such research.

In addition, section 472(a)(1)(B) of the Public Health Service Act, as so added, directed the Secretary to make grants to non-Federal public and nonprofit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research (and training to undertake such research) in matters described in item (1) of the preceding paragraph.

Notice is hereby given that the Assistant Secretary for Health, with the approval of the Secretary of Health, Education, and Welfare, proposes to adopt the regulations set forth below for the purpose of implementing the foregoing legislation.

Written comments concerning the proposed regulations are invited from interested persons. Inquiries may be addressed, and data, views, and arguments relating to the regulations may be presented in writing in triplicate to the Training Officer, Office of the Director, National Institutes of Health, Building 1, Room 117, 9000 Rockville Pike, Bethesda, Maryland 20014. All comments received will be available for public inspection at said Office on weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m. All relevant material received on or before February 18, 1975 will be considered.

Notice is also given that it is proposed to make any amendments that are adopted effective upon publication in the FEDERAL REGISTER.

Dated: December 13, 1974.

CHARLES C. EDWARDS,  
Assistant Secretary for Health.

Approved: January 8, 1975.

CASPAR W. WEINBERGER,  
Secretary.

It is therefore proposed to amend Title 42 of the Code of Federal Regulations by adding the following new Part 66:

PART 66—NATIONAL RESEARCH SERVICE  
AWARDS

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AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 472, 88 Stat. 342 (42 U.S.C. 2891-1).

## Subpart A—Direct Awards

## § 66.101 Applicability.

The regulations in this subpart are applicable to National Research Service Awards by the Secretary, under section 472(a)(1)(A) of the Public Health Service Act, as amended (42 U.S.C. 289v-1(a)(1)(A)), to individuals for: (a) Biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration in matters relating to the cause, diagnosis, prevention, and treatment of the disease (or diseases) or other health problems to which the activities of NIH and ADAMHA are directed, (b) training at NIH and ADAMHA of individuals to undertake such research, (c) biomedical and behavioral research at non-Federal public and nonprofit private institutions, and (d) predoctoral and postdoctoral training at such institutions of individuals to undertake such research.

## § 66.102 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and

Welfare to whom the authority involved has been delegated.

(c) "NIH" means the National Institutes of Health.

(d) "ADAMHA" means the Alcohol, Drug Abuse, and Mental Health Administration.

(e) "Nonprofit" as applied to any institution means an institution which is a corporation or association no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

(f) "Award" means a National Research Service Award under section 472 of the Act (42 U.S.C. 2891-1).

(g) "Residency" means post-graduate training, for doctors of medicine, osteopathy, and dentistry, nurses, and other individuals providing health care directly to patients, where the majority of the time is spent in non-research clinical training.

(h) "National Health Service Corps" means the Corps referred to in section 329 of the Act (42 U.S.C. 254b).

(i) "Noncitizen national of the United States" means a person who, though not a citizen of the United States, owes permanent allegiance to the United States (8 U.S.C. 1101(a)(22)).

(j) "Predoctoral training" means training at the post-baccalaureate level in a program leading to the award of a doctor of philosophy or science.

(k) "Postdoctoral training" means training of individuals holding a doctor of philosophy, science, medicine, dentistry, osteopathy, veterinary medicine, engineering, nursing sciences, public health, or equivalent degree.

## § 66.103 Eligibility.

To be eligible for a National Research Service Award under this subpart an individual must:

(a) Be a citizen or noncitizen national of the United States or have been lawfully admitted to the United States for permanent residence at the time of application; and

(b) Propose to engage in full-time biomedical or behavioral research, or training to undertake such research, at NIH, ADAMHA, or a non-Federal public or nonprofit private institution.

## § 66.104 Application.

(a) Application for an Award under this subpart shall be made on a form approved for that purpose by the Secretary. The completed form, executed by the individual applicant, shall be submitted to NIH or ADAMHA on or before such dates as the Secretary may prescribe.

(b) In addition to any other pertinent information that the Secretary may require, each application shall set forth in detail:

(1) The applicant's educational background and other qualifications and experience;

(2) The subject area of the proposed research or training;

(3) The proposed period of Award;

(4) If the proposed period of Award is in excess of three years, the justifications for such request; and

(5) The availability of the institution where the research or training would be conducted of resources and facilities necessary to carry out such research or training.

#### § 66.105 Requirements.

No Award shall be made to an individual under this subpart unless:

(a) The individual has submitted to the Secretary a written assurance (in such form as the Secretary may prescribe) that he or she will satisfy the requirements of paragraphs 66.110(a) and 66.110(b) of this subpart;

(b) If the proposed research or training would take place at a non-Federal institution, such institution has submitted a written assurance (in such form as the Secretary may prescribe), executed by a representative of the institution authorized to act for the institution and to assume on behalf of the institution the obligations imposed by the terms and conditions of the Award including the regulations of this subpart, indicating that the applicant has been accepted to the institution for the purpose of engaging in the research or training for which an Award is being sought, that the Award is not to be used to support a residency, and that, in the event an Award is made, the institution will make available to the applicant any resources and facilities described in the application as necessary to carry out such research or training;

(c) Effective July 1, 1975, the proposed research or training is in a subject area for which there is a need for personnel, as determined under section 473 of the Act (42 U.S.C. 2891-2); and

(d) The individual has submitted a written assurance (in such form as the Secretary may prescribe) that the Award is not to be used to support a residency.

#### § 66.106 Awards.

(a) Within the limits of funds available, the Secretary shall make Awards to those applicants:

(1) Whose applications have been reviewed and recommended for approval by appropriate advisory councils within NIH and ADAMHA;

(2) Who have satisfied the requirements of § 66.105 of this subpart; and

(3) Whose proposed research or training would, in the judgment of the Secretary, best promote the purposes of section 472(a)(1)(A) of the Act, taking into consideration among other pertinent factors:

(i) The scientific, technical, or educational merit of the particular proposal;

(ii) The availability of resources and facilities to carry it out;

(iii) The qualifications and experience of the applicant; and

(iv) The degree of the need for personnel in the subject area of the proposed research or training.

(b) All Awards shall be in writing and shall specify the proposed period of the Award (which may not exceed three years in the aggregate for any individual unless the Secretary for good cause shown waives the application of this limitation to such individual), the stipends

and allowances provided and the levels thereof during the initial year of said period (see § 66.107), the estimated levels for future years, and (if the Award is made for research or training at a non-Federal institution) the amount of the payments to the institution for the cost of services provided the awardee by such institution during the initial year of said period (see § 66.108).

(c) In determining what constitutes "good cause" for purposes of paragraph (b) of this section, the Secretary shall take into account such factors as whether the applicant proposes to complete both predoctoral and postdoctoral training programs under the Award.

#### § 66.107 Payments to awardees.

(a) Individuals receiving Awards shall be entitled to such stipends and allowances as the Secretary may designate, taking into account such factors as the needs of the program, the cost of living, and the availability of funds.

(b) Payments of stipends and allowances shall, at the discretion of the Secretary, be made to the awardee or the sponsoring institution for payment to the awardee.

#### § 66.108 Payments to institutions.

(a) Where an Award is made to an individual under this subpart for research or training at a non-Federal public or nonprofit private institution, the institution shall be entitled to an allowance to help defray the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by the institution. The amount of any such payments to any institution shall be determined by the Secretary based upon the reasonable costs to the institution of establishing and maintaining the quality of its biomedical and behavioral research and training programs.

(b) Payments to the institution under this section may be made either in advance or by way of reimbursement, as prescribed by the Secretary.

#### § 66.109 Termination.

(a) The Secretary may terminate an Award prior to its normal expiration date:

(1) At the written request of the awardee; or

(2) If the Secretary finds that the awardee has materially failed to comply with the terms and conditions of the Award or to carry out the purpose for which it was made.

(b) In the event an Award is terminated the Secretary shall notify the awardee in writing of this determination, the reasons therefor, the effective date, and any procedural rights available.

#### § 66.110 Service, payback, and recovery requirements.

(a) Each individual who receives an Award shall upon completion thereof:

(1) Engage in biomedical or behavioral research or teaching for a period equal to the period of support, or

(2) If the Secretary determines that there are no suitable research or teaching positions available to such individual, and if such individual is a physician, dentist, nurse, or other individual trained to provide health care directly to individual patients, and if the Secretary so authorizes such individual, in lieu of engaging in research or training:

(i) Serve as a member of the National Health Service Corps for a period equal to the period of support;

(ii) Serve in his specialty in private practice in a geographic area designated by the Secretary as requiring that specialty for 20 months for each twelve months of support; or

(iii) Provide services in his specialty for a health maintenance organization to which payments may be made under section 1876 of Title XVIII of the Social Security Act and which serves an underserved population (as defined in section 1302(7) of the Act) for 20 months for each 12 months of support; or

(3) If the Secretary determines that there are no suitable research or teaching positions available to an individual, and if such individual is not trained to provide health care directly to individual patients, and if the Secretary so authorizes such individual, in lieu of engaging in research or teaching, engage in a health-related activity for 20 months for each 12 months of support.

(b) Except as provided in section 111 of this subpart, an individual to whom the requirement for service in paragraph (a) of this section is applicable must begin to undertake such service on a continuous basis within two years after the termination of his or her Award.

(c) If an individual fails to undertake or perform such service in accordance with the requirements of paragraph (b) of this section, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula:

$$A = \theta t - \left(\frac{1}{2}\right) s$$

in which "A" is the amount the United States is entitled to recover; "θ" is the sum of the total amount of stipends paid under one or more Awards to such individual and the interest on such amount which would be payable if at the time it was paid it was a loan bearing interest at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing at the time the Award was made; "t" is total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by him in accordance with paragraph (a) of this section.

(d) Except as provided in § 66.111 of this subpart, any amount which the United States is entitled to recover under paragraph (c) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under paragraph (c) of this section on account of any Award is paid,



there shall accrue to the United States interest on such amount at the same rate as that fixed by the Secretary of the Treasury under paragraph (c) of this section to determine the amount due the United States.

**§ 66.111 Suspension, waiver, and cancellation.**

(a) The Secretary may extend the period for undertaking service prescribed in § 66.110(b) of this subpart, permit breaks in service under said paragraph, or extend the period for repayment under § 66.110(d) if the Secretary determines that:

(1) Such an extension or break in service is necessary so the individual may complete his or her research training;

(2) Completion during said period would be impossible because the individual is temporarily disabled; or

(3) Completion during said period would involve an extreme hardship to such individual and failure to extend such period would be against equity and good conscience.

(b) The Secretary may waive the obligation of such individual to repay pursuant to § 66.110(c) if the Secretary determines that:

(1) Fulfillment would be impossible because the individual is permanently and totally disabled; or

(2) Fulfillment would involve an extreme hardship to such individual and enforcement of such obligation would be against equity and good conscience.

(c) In making determinations under §§ 66.111(a)(3) and (b)(2), the Secretary will take into consideration such factors as:

(1) The individual's present financial resources and obligations;

(2) The individual's estimated future financial resources and obligations;

(3) The reasons for the individual's failure to complete such requirements within the prescribed period, such as problems of a personal nature; and

(4) The extent to which the individual has been engaged in activities encompassed by § 66.110(a).

(d) Any obligation of any individual under this subpart will be cancelled upon the death of such individual.

**§ 66.112 Nondiscrimination.**

Attention is called to the fact that funds paid to an institution under § 66.108 of this subpart are considered Federal financial assistance to such institution. The institution is thus subject to:

(a) The prohibition against discrimination on the basis of race, color, or national origin imposed by Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and the implementing regulation of the Department of Health, Education, and Welfare (45 CFR Part 80); and

(b) The prohibition against discrimination on the basis of sex imposed by Title IX of the Education Amendments of 1972 and in particular section 901 of such Act.

**§ 66.113 Human subjects; animal welfare.**

Where the application is for research or training at a non-Federal public or non-profit private institution, no Award may be made under this subpart unless said institution has complied with:

(a) 45 CFR Part 46 and any other applicable requirements pertaining to the protection of human subjects.

(b) Chapter 1-43 of the Department of Health, Education, and Welfare Grants Administration Manual<sup>1</sup> and any other applicable requirements concerning animal welfare.

**§ 66.114 Publications.**

Publication, distribution, and disposition of all manuscripts and other materials resulting from an Award shall be subject to the conditions that all such materials shall bear appropriate acknowledgment of Department of Health, Education, and Welfare support and that the awardee shall furnish such copies of these manuscripts or other materials as the Secretary may reasonably request.

**§ 66.115 Copyright.**

Where the work accomplished under an Award results in a book or other copyrightable material, the author is free to copyright the work, but the United States reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use, and to authorize others to use, all copyrightable or copyrighted material resulting from the Award.

**§ 66.116 Inventions and discoveries.**

(a) Any Award is subject to the regulations of the Department of Health, Education, and Welfare set forth in 45 CFR Parts 6 and 8, as amended. Such regulations shall apply to any activity for which Award funds are in fact used, whether within the scope of the Award as approved or otherwise. Each such invention or discovery shall be promptly and fully reported to the Assistant Secretary for Health, Department of Health, Education, and Welfare.

(b) Determination as to ownership and disposition of rights to such invention or discovery, including whether a patent application shall be filed, and, if so, the manner of obtaining, administering, and disposing of rights under any patent application or patent which may issue shall be made either:

(1) By the Assistant Secretary for Health, whose decision shall be final, or

(2) Where an Award is made to an individual for research or training at a non-Federal public or nonprofit private institution having a separate formal institutional patent agreement with the Department of Health, Education, and

<sup>1</sup>The Department of Health, Education, and Welfare Grants Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR § 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Welfare, by the institution in accordance with that agreement.

**§ 66.117 Additional conditions.**

The Secretary may with respect to any Award or class of Awards impose additional conditions prior to or at the time of any Award when in his judgment such conditions are necessary to assure the carrying out of the purposes of the Award, the interests of the public health, or the conservation of funds awarded.

**Subpart B—Institutional Growth**

**§ 66.201 Applicability.**

The regulations in this subpart are applicable to grants under section 472(a)(1)(B) of the Public Health Service Act, as amended (42 U.S.C. 2891-1(a)(1)(B)), to non-Federal public institutions and to nonprofit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research and predoctoral and postdoctoral training to undertake such research in matters relating to the cause, diagnosis, prevention, and treatment of the disease (or diseases) or other health problems to which the activities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration are directed.

**§ 66.202 Definitions.**

The definitions in § 66.102 of subpart A of this part shall apply as well to this subpart.

**§ 66.203 Eligibility.**

To be eligible for a grant under this subpart, an applicant must be:

(a) A non-Federal public or nonprofit private institution; and

(b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

**§ 66.204 Application.**

(a) Each institution desiring a grant under this subpart shall submit an application on a form approved for that purpose by the Secretary, on or before such dates as the Secretary may prescribe. Such application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart.

(b) In addition to any other pertinent information that the Secretary may require, each application shall set forth in detail:

(1) The subject area or areas in which the proposed research or training will be conducted;

(2) The resources and facilities available to the applicant for use by recipients of Awards in carrying out such research or training;

(3) The names, qualifications, and experience of the program director and

principal staff members who will be responsible for the proposed program;

(4) The criteria to be employed in selecting individuals to be recipients of Awards;

(5) The estimated number of recipients of Awards under the grant;

(6) The proposed period of support and a detailed budget and justification for the amount of grant funds requested; and

(7) Proposed methods for monitoring and evaluating the performance of individual recipients of Awards, as well as the overall program.

**§ 66.205 Requirements.**

(a) No Award shall be made to an individual under a grant pursuant to this subpart unless:

(1) The individual has submitted to the Secretary a written assurance (in such form as the Secretary may prescribe) that he or she will satisfy the requirements of §§ 66.110 (a) and (b) of subpart A of this part;

(2) Effective July 1, 1975, such Award is for research or training in a subject area for which there is a need for personnel, as determined under section 473 of the Act (42 U.S.C. 2891-2);

(3) The individual is a citizen or non-citizen national of the United States or has been lawfully admitted to the United States for permanent residence at the time of application;

(4) The Award includes a provision for termination in the event the recipient is found by the institution to have materially failed to comply with the terms and conditions of the Award or to carry out the purpose for which it was made; and

(5) The Award is not to be used to support a residency.

(b) No Award shall be made to an individual under such grant which exceeds three years in the aggregate unless the Secretary for good cause shown as provided in § 66.106(c) of subpart A of this part, waives the application of this limitation to such individual.

(c) The provisions of §§ 66.110 and 66.111 of subpart A of this part constitute terms and conditions of any Award made under a grant pursuant to this subpart.

**§ 66.206 Grant awards.**

(a) Within the limits of funds available, the Secretary shall award grants to those applicants:

(1) Whose applications have been reviewed and recommended for approval by appropriate advisory councils within NIH and ADAMHA;

(2) Who have satisfied the requirements of § 66.205 of this subpart; and

(3) Whose proposed programs would, in the judgment of the Secretary, best promote the purposes of section 472(a) (1) (B) of the Act, taking into consideration among other pertinent factors:

(i) The scientific, technical, or educational merit of the proposed program;

(ii) The adequacy of the resources and facilities available to the applicant;

(iii) The qualifications and experience of the program director and principal staff members;

(iv) The degree of the need for personnel in the subject area of the proposed research or training;

(v) The administrative and managerial capability of the applicant;

(vi) The reasonableness of the proposed budget in relation to the proposed program; and

(vii) The adequacy of the methods for monitoring and evaluating the performance of individual recipients and the overall program.

(b) All grant awards shall be in writing and shall specify the proposed period of support, the approved budget for the initial budget period, the total recommended amount of funds for the entire period of support, the amount awarded for the initial budget period, and the estimated amounts for future years.

(c) Neither the approval of any application nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other grant award with respect to any approved application or portion thereof.

(d) The amount of any grant award shall be determined by the Secretary on the basis of his estimate of the sum necessary during the budget period: (1) To provide stipends and allowances to individual recipients of Awards and payments to the institution, as determined in accordance with §§ 66.107(a) and 66.108(a) of subpart A of this part, and (2) otherwise to carry out the grant award.

**§ 66.207 Payment.**

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement, for expenses incurred or to be incurred in accordance with its approved application.

**§ 66.208 Expenditure of grant funds.**

(a) Any funds granted pursuant to this subpart shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed by subpart Q of 45 CFR Part 74.

(b) Any unobligated grant funds remaining in the grant account at the close of a budget period may, with prior approval by the Secretary, be carried forward and remain available for obligation during the remainder of the period of support, subject to such limitations as the Secretary may prescribe. The amount of any subsequent award will take into consideration unobligated grant funds remaining in the grant account. At the end of the final period of support any unobligated grant funds remaining in the grant account must be refunded to the United States.

**§ 66.209 Nondiscrimination.**

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) which provides that no person in

the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which is applicable to grants made under this subpart, has been issued by the Secretary of Health, Education, and Welfare with the approval of the President (45 CFR Part 80).

(b) Attention is also called to the requirements of Title IX of the Education Amendments of 1972 and in particular to section 901 of such Act which provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.

(c) Grant funds used for alterations and renovations shall be subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

**§ 66.210 Human subjects; animal welfare.**

No grant award may be made under this subpart unless the applicant has complied with:

(a) 45 CFR Part 46 and any other applicable requirements pertaining to the protection of human subjects.

(b) Chapter 1-43 of the Department of Health, Education, and Welfare Grants Administration Manual<sup>1</sup> and any other applicable requirements concerning animal welfare.

**§ 66.211 Applicability of 45 CFR Part 74.**

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to all other grantee organizations under this subpart:

- 45 CFR PART 74
- Subpart
- A General.
  - B Cash Depositories.
  - C Bonding and Insurance.
  - D Retention and Custodial Requirements for Records.
  - F Grant-Related Income.
  - G Matching and Cost Sharing.
  - K Grant Payment Requirements.
  - M Grant Closeout Suspension, and Termination.
  - O Property.
  - Q Cost Principles.

<sup>1</sup>The Department of Health, Education, and Welfare Grants Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR § 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

## PROPOSED RULES

**§ 66.212 Progress and fiscal records and reports.**

Each grant award shall require that the grantee maintain such progress and fiscal records and file with the Secretary, such progress and fiscal reports relating to the conduct and results of the approved grant and the use of grant funds as the Secretary may find necessary to carry out the purposes of this subpart.

**§ 66.213 Grantee accountability.**

(a) All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved program the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available to the Secretary, satisfactory evidence of expenditures for direct and indirect costs meeting the requirements of this subpart.

(b) Accounting for royalties. Royalties received by grantees from copyrights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under such grant, shall be accounted for as follows:

(1) State and local governments. Where the grantee is a State or local government as those terms are defined in subpart A of 45 CFR Part 74, royalties shall be accounted for as provided in 45 CFR 74.44.

(2) Grantees other than State and local governments. Where the grantee is not a State or local government as those terms are defined in subpart A of 45 CFR Part 74, royalties shall be accounted for as follows:

(i) Patent royalties, whether received during or after the grant period, shall be governed by agreements between the Assistant Secretary for Health, Department of Health, Education, and Welfare, and the grantee, pursuant to the Department's patent regulations (45 CFR Parts 6 and 8).

(ii) Copyright royalties, whether received during or after the grant period, shall first be used to reduce the Federal share of the grant to cover the costs of publishing or producing the materials, and any royalties in excess of the costs of publishing or producing the materials shall be distributed in accordance with Chapter 1-420 of the Department of Health, Education, and Welfare Grants Administration Manual.

**§ 66.214 Publications and copyright.**

(a) State and local governments. Where the grantee is a State or local government as those terms are defined in

subpart A of 45 CFR Part 74, the Department of Health, Education, and Welfare copyright requirement set forth in 45 CFR 74.140 shall apply with respect to any book or other copyrightable materials developed or resulting from an activity supported by a grant under this subpart.

(b) Grantees other than State and local governments. Where the grantee is not a State or local government as those terms are defined in subpart A of 45 CFR Part 74, except as may otherwise be provided under the terms and conditions of the grant award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from an activity supported by a grant under this subpart, subject to a royalty-free non-exclusive, and irrevocable license or right in the United States to reproduce, translate, publish, use, disseminate and dispose of such materials, and to authorize others to do so.

**§ 66.215 Additional conditions.**

The Secretary, may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

[FR Doc. 75-1166 Filed 1-16-75; 8:45 am]

