

- 42 CFR part 52h—Scientific peer review of research grant applications and research and development contract projects
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 46—Protection of human subjects
- 45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments
- 45 CFR part 93—New restrictions on lobbying
- 59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

[NOTE: This policy is subject to change, and interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, Bethesda, MD 20892-0161 (301-402-1770; not a toll-free number) to obtain references to the current version and any amendments.]

- 59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules.

NOTE: This policy is subject to change, and interested persons should contact the Office of Recombinant DNA Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010 (301-496-9838; not a toll-free number) to obtain references to the current version and any amendments.]

“PHS Grants Policy Statement,” DHHS Publication No. (OASH) 94-50,000 (Revised April 1, 1994), as amended by Addendum, dated January 24, 1995.

NOTE: This policy is subject to change, and interested persons should contact the Extramural Outreach and Information Resources Office (EOIRO), Office of Extramural Research, 6701 Rockledge Drive, Room 6208, MSC 7910, Bethesda, MD 20892-7910 (301-435-0714; not a toll-free number) to obtain references to the current version and any amendments. Information may also be obtained by contacting the EOIRO via its e-mail address (asknih@odrockml.od.nih.gov) and by browsing the NIH Home Page site on the World Wide Web (<http://www.nih.gov>).]

“Public Health service Policy on Humane Care and Use of Laboratory animals,” Office for Protection from Research Risks, HHS (Revised September 1986).

NOTE: This policy is subject to change, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20852-7507 (301-496-7005; not a toll-free number) to obtain references to the current version and any amendments.]

PART 66—NATIONAL RESEARCH SERVICE AWARDS

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AUTHORITY: 42 U.S.C. 216, 288.

SOURCE: 48 FR 24880, June 3, 1983, unless otherwise noted.

Subpart A—Direct Awards

§ 66.101 Applicability.

The regulations in this subpart apply to National Research Service Awards made by the Secretary to individuals for research and training to undertake research, under section 487 of the Public Health Service Act, as amended (42 U.S.C. 288).

[66 FR 29499, May 31, 2001]

§ 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 and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) *Nonprofit* institution means a corporation or association in which no part of the net earnings inures or may lawfully inure to the benefit of any private shareholder or individual.

(d) *Award* means a National Research Service Award under section 487 of the Act (42 U.S.C. 288).

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

(f) *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)].

(g) *Predoctoral training* means training at the post-baccalaureate level in a program leading to the award of a doctor of philosophy of science, or equivalent degree. For purposes of Awards under the Minority Access to Research Careers programs of the National Institute of General Medical Sciences and the Career Opportunities in Research Education and Training programs of the National Institute of Mental Health, *predoctoral training* also means training in a program leading to the

award of a baccalaureate in science or equivalent degree.

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

[48 FR 24880, June 3, 1983, as amended at 66 FR 29499, May 31, 2001]

§ 66.103 Eligibility.

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

(a) Be a citizen, noncitizen national of the United States, or lawfully admitted to the United States for permanent residence at the time of the award.

(b) Propose to engage in such research, or training to undertake research, in a program specified in section 487(a)(1)(A) of the Act; and

(c) Propose to engage in such research or training to undertake research on a full-time basis except in cases of disability or pressing family need.

[48 FR 24880, June 3, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.104 Application.

(a) Eligible individuals may apply for an Award using the form and by the dates the Secretary prescribes.

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

(1) The applicant's educational background and other qualifications and experience, including previous academic and professional degrees;

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

(3) The proposed period of Award;

(4) If the proposed period of Award would provide the individual with aggregate support in excess of five years at the predoctoral level or three years at the postdoctoral level, the justification for this request; and

(5) The availability of necessary resources and facilities at the institution

where the research or training would be conducted.

(Approved by the Office of Management and Budget under control number 0925-0002)

[48 FR 24880, June 3, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.105 Requirements.

The Secretary shall make an Award to an individual under this subpart only if:

(a) For any Award made for an individual's initial twelve months of NRSA postdoctoral research or training, the individual has assured the Secretary, in the form and manner the Secretary may prescribe, that he or she will satisfy the requirements of § 66.110.

(b) If the proposed research or training would take place at an institution other than the National Institutes of Health, the institution has assured the Secretary, in the form and manner the Secretary may prescribe, that:

(1) 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;

(2) The Award will not be used to support a residency; and

(3) 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 the research or training; and

(c) The individual has assured the Secretary, in the form and manner the Secretary may prescribe, that the Award to the individual will not be used to support a residency.

(Approved by the Office of Management and Budget under control number 0925-0002)

[48 FR 24880, June 3, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.106 Awards.

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

(1) Who have satisfied the requirements of § 66.105; and

(2) Whose proposed research or training would, in the judgment of the Secretary, best promote the purposes of section 487(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 need for personnel in the subject area of the proposed research or training.

(b) In making Awards, the Secretary shall take account of the Nation's overall need for biomedical research by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(c) All Awards shall be in writing. Each shall specify:

(1) The period of the Award;

(2) The total recommended stipends and allowances provided for the entire Award period;

(3) The amount awarded for the initial year of that period (see § 66.107); and

(4) The amount of the payments to the institution for the cost of services provided the awardee by the institution during the initial year of that period (see § 66.108).

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

(e) No individual may receive an aggregate of more than five years of support at the predoctoral level and three years at the postdoctoral level unless the Secretary waives, for good cause shown, this limitation for the individual. In determining what constitutes "good cause," the Secretary shall take into account such factors as whether the applicant proposes to pursue a combined program leading to the degrees of doctor of medicine and doctor of philosophy.

[48 FR 24880, June 3, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.107 Payments to awardees.

(a) Individuals receiving Awards shall be entitled to the stipends, tuition, fees, and allowances the Secretary may designate, taking into account the cost

§ 66.108

of living, and such other factors as the needs of the program and the availability of funds.

(b) The Secretary shall pay stipends, tuition, fees and allowances to the awardee or the sponsoring institution for payment to the awardee.

§ 66.108 Payments to institutions.

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 to the individual by the institution. The Secretary shall determine the amount of payments based upon reasonable costs to the institution of establishing and maintaining the quality of research and training programs for which it receives support under this subpart. The Secretary may make payments to the institution either in advance or by way of reimbursement.

§ 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 for termination, the effective date, and any procedural rights available.

§ 66.110 Service, payback, and recovery requirements.

(a) Each individual who receives an Award for postdoctoral research or training shall engage in a month of research training, research, or teaching that is health-related (or any combination thereof) for each month of support received, up to a maximum of twelve months. Such period shall be served in accordance with the usual patterns of such employment or training.

(b) In any case in which an individual receives an Award for more than twelve months, the thirteenth month

and each subsequent month of performing activities under the Award shall be considered to be activities toward satisfaction of the requirement established in paragraph (a) of this section.

(c) Except as provided in § 66.111, an individual subject to the requirements for service in paragraph (a) of this section must begin to undertake the service on a continuous basis within two years after the expiration or termination for his or her Award.

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

$$A = O \frac{(t-s)}{t}$$

In which

A is the amount the United States is entitled to recover;

O is the sum of the total amount paid to the individual for the months of postdoctoral support up to a maximum of twelve months; *t* is total number of months in the individual's service obligation;

and *s* is the number of months of the obligation served by him or her in accordance with paragraph (a) or (b) of this section.

(e) Except as provided in § 66.111, the individual shall pay to the United States any amount which it is entitled to recover under paragraph (d) of this section within a three-year period beginning on the date the United States becomes entitled to recovery that amount. Interest shall accrue to the United States until any amount due it under paragraph (d) of the section is paid. The rate of interest will be fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to recovery.

[66 FR 29500, May 31, 2001]

§ 66.111 Suspension, waiver, and cancellation.

(a) The Secretary may extend the period for undertaking service described in § 66.110(c), permit breaks in the continuous service required under

§ 66.110(c), or extend the period of repayment under § 66.110(e) if the Secretary determines that:

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

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

(3) Completion during the period would involve a substantial hardship to the individual and failure to extend to the period would be against equity and good conscience.

(b) The Secretary may waive, in whole or in part, the obligation of the individual to repay pursuant to § 66.110(d) if the Secretary determines that:

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

(2) Fulfillment would involve a substantial hardship to the individual and enforcement of the 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 the requirements within the prescribed period, such as problems of a personal nature;

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

(5) Whether the individual has received sufficient training to be qualified to perform any such activities;

(6) The unavailability of employment opportunities appropriate to the individual's education and training; and

(7) Any other extenuating circumstances.

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

[48 FR 24880, June 3, 1983; 48 FR 33710, July 25, 1983, as amended at 66 FR 29500, May 31, 2001]

§ 66.112 Other HHS regulations and policies that apply.

Several other regulations and policies may apply to individuals and institutions receiving payments under this subpart. These include, but are not limited to:

45 CFR part 46—Protection of human subjects

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this Title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

51 FR 16958 (May 7, 1986)—NIH Guidelines for Research Involving Recombinant DNA Molecules.

NOTE: This policy is subject to change, and interested persons should contact the Office of Science Policy, Office of Biotechnology Activities, NIH, Suite 302, 6000 Executive Boulevard, MSC 7052, Bethesda, MD 20892-7052, (301) 496-9838 (not a toll-free number) to obtain references to the current version and any amendments.

[49 FR 38116, Sept. 27, 1984, as amended at 66 FR 29500, May 31, 2001]

§ 66.113 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 acknowledgement of Department of Health and Human Services support and that the awardee shall furnish copies of these manuscripts or other materials as the Secretary may reasonably request.

§ 66.114 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.

§ 66.115 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 the Secretary's 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 Grants

§ 66.201 Applicability.

The regulations in this subpart apply to grants under section 487 of the Public Health Service Act, as amended (42 U.S.C. 288), to public institutions and to nonprofit private institutions to enable those institutions to make National Research Service Awards to individuals for research and training to undertake research, in programs specified in section 487 of the Act.

[66 FR 29500, May 31, 2001]

§ 66.202 Definitions.

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

[48 FR 24880, June 3, 1983; 48 FR 33710, July 25, 1983]

§ 66.203 Eligibility.

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

- (a) A 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) Application for a grant under this subpart shall be made on a form approved for that purpose by the Secretary. Applicants shall submit completed forms on or before the dates 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 subject area or areas in which the proposed research or training will be conducted;
- (2) The resources and facilities available for use by recipients of Awards in carrying out this 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 recipients of Awards;
- (5) The estimated number of recipients of Awards under the grant;
- (6) The proposed project period 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.

(Approved by the Office of Management and Budget under control number 0925–0022)

§ 66.205 Requirements.

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

- (1) For any award made for an individual's initial twelve months of NRSA postdoctoral research training, the individual has assured the Secretary, in the form and manner the Secretary may prescribe, that he or she will satisfy the requirements of § 66.110 of subpart A of this part;
 - (2) 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 the award;
 - (3) 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
 - (4) The Award is not to be used to support a residency.
- (b) No Award shall be made to an individual under such grant which would provide that individual with aggregate support in excess of five years for

predoctoral training and three years for postdoctoral training, unless the Secretary for good cause shown as provided in §66.106(e) of subpart A of this part, waives the application of the limitation with respect to that individual;

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

(Approved by the Office of Management and Budget under control number 0925-0022)

[48 FR 24880, June 3, 1983; 48 FR 33710, July 25, 1983, as amended at 66 FR 29501, May 31, 2001]

§ 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 the appropriate national advisory council or board;

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

(3) Whose proposed programs would, in the judgment of the Secretary, best promote the purposes of section 487(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 or areas of the proposed research or training;

(v) The extent to which the applicant, in making Awards, gives special consideration to physicians who agree to undertake a minimum of two years of biomedical research;

(vi) The administrative and management capability of the applicant;

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

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

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to re compete for funds. This period, called the project period, will usually be for 3-5 years.

(c) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of any approved application.

[48 FR 24880, June 3, 1983, as amended at 66 FR 29501, May 31, 2001]

§ 66.207 Other HHS regulations and policies that apply.

Several other regulations and policies apply to grants under this subpart. These include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

42 CFR part 50, subpart F—Responsibility of applicants for promoting objectivity in research for which PHS funding is sought.

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments.

45 CFR part 75—Informal grant appeals procedures

45 CFR part 76—Governmentwide debarment and suspension (non procurement) and governmentwide requirements for drug-free workplace (grants)

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- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
- 48 FR 24556—Guidelines for Research Involving Recombinant DNA Molecules published by the National Institutes of Health
- 51 FR 16958 (May 7, 1986)—NIH Guidelines for Research Involving Recombinant DNA Molecules.

NOTE: This policy is subject to change, and interested persons should contact the Office of Biotechnology Activities, NIH, Suite 302, 6000 Executive Boulevard, MSC 7052, Bethesda, MD 20892-7052, (301) 496-9838 (not a toll-free number) to obtain references to the current version and any amendments.

[49 FR 38116, Sept. 27, 1984, as amended at 66 FR 29501, May 31, 2001]

EDITORIAL NOTE: At 66 FR 20752, May 31, 2001, in § 66.207, the entry for 48 FR 24556 was revised. However, no new entry was set forth.

§ 66.208 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 the Secretary's judgment those conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

PART 67—AGENCY FOR HEALTH CARE POLICY AND RESEARCH GRANTS AND CONTRACTS

Subpart A—Research Grants for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

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- 67.10 Purpose and scope.
67.11 Definitions.
67.12 Eligible applicants.
67.13 Eligible projects.
67.14 Application.
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- 67.16 Evaluation and disposition of applications.
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67.18 Use of project funds.
67.19 Other applicable regulations.
67.20 Confidentiality.
67.21 Control of data and availability of publications.
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Subpart B—Peer Review of Contracts for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

- 67.101 Purpose and scope.
67.102 Definitions.
67.103 Peer review of contract proposals.
67.104 Confidentiality.
67.105 Control of data and availability of publications.

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SOURCE: 62 FR 12908, Mar. 18, 1997, unless otherwise noted.

Subpart A—Research Grants for Health Services Research, Evaluation, Demonstration, and Dissemination Projects

§ 67.10 Purpose and scope.

The regulations of this subpart apply to the award by AHCPH of grants and cooperative agreements under:

(a) Title IX of the Public Health Service Act to support research, evaluation, demonstration, and dissemination projects, including conferences, on health care services and systems for the delivery of such services, as well as to establish and operate multidisciplinary health services research centers.

(b) Section 1142 of the Social Security Act to support research on the outcomes, effectiveness, and appropriateness of health care services and procedures, including but not limited to, evaluations of alternative services and procedures; projects to improve methods and data bases for outcomes, effectiveness, and other research; dissemination of research information and clinical guidelines, conferences, and research on dissemination methods.