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concept for behavioral or biomedical research and development contracts is not needed if one of the following circumstances applies: the solicitation is to re-compete or extend a project that is within the scope of a current project that has been peer reviewed, or there is a Congressional authorization or mandate to conduct specific contract projects. If a substantial amount of time has passed since the concept review, the awarding official shall determine whether peer review is required to ensure the continued scientific merit of the concept.

(d) Except to the extent otherwise provided by law, the recommendations referred to in this section are advisory only and not binding on the awarding official.

§ 52h.11 What are the review criteria for contract projects and proposals?

(a) In carrying out its review of a project concept under § 52h.10(a) or § 52h.10(b), the peer review group shall take into account, among other pertinent factors:

(1) The significance from a scientific or technical standpoint of the goals of the proposed research or development activity;

(2) The availability of the technology and other resources necessary to achieve those goals;

(3) The extent to which there are identified, practical uses for the anticipated results of the activity; and

(4) Where the review includes the project approach, the adequacy of the methodology to be utilized in carrying out the activity.

(b) In carrying out its review of unsolicited contract proposals under § 52h.9, the peer review group shall take into account, among other pertinent factors, the criteria in § 52h.8 which are relevant to the particular proposals.

(c) In carrying out its review of solicited proposals under § 52h.10(a) or (b), the peer review group shall evaluate each proposal in accordance with the criteria set forth in the request for proposals.

§ 52h.12 Other regulations that apply.

The regulations in this part are in addition to, and do not supersede other regulations concerning grant applica-

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tions, contract projects, or contract proposals set forth elsewhere in this title, title 45, or title 48 of the Code of Federal Regulations.

PART 52i—JOHN LEWIS NIMHD RESEARCH ENDOWMENT PROGRAM

Sec.

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AUTHORITY: 42 U.S.C. 216, 285t–285t–1.

SOURCE: 80 FR 53744, Sept. 8, 2015, unless otherwise noted.

§ 52i.1 To what program does this part apply?

This part applies to grants awarded under section 464z–3(h) of the Public Health Service Act (the Act), which authorizes the Director of the National Institute on Minority Health and Health Disparities (NIMHD) to carry out a program of research endowment grants to eligible institutions to facilitate minority health and health disparities research (the NIMHD Research Endowment Program), and, with the exception of §§ 52i.5 and 52i.6, applies to that portion of an award made under section 464z–4(f) of the Act authorized by the NIMHD Director for research endowment.

§ 52i.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Center of Excellence means, for purposes of grants authorized by section 464z-3(h) of the Act, an institution designated as a Center of Excellence and receiving a grant under section 736 (42 U.S.C. 293) or section 464z-4 (42 U.S.C. 285t-1) of the Act.

Director means the Director, NIMHD, of the National Institutes of Health.

Endowment fund means a fund that is established by state law, by an institution, or by a foundation associated with an institution that is exempt from taxation and is maintained for the purpose of generating income for the support of minority and health disparities research or research training if the funds are from a grant made under section 464z-3 of the Act. The principal or corpus of the fund may not be spent except as noted in § 52i.8(b).

Endowment fund corpus means an amount equal to the total grant funds awarded under this part or equal to the amount designated as endowment under section 464z-4 of the Act.

Endowment fund income means the income generated from investing the corpus, *i.e.*, the amount of which exceeds the endowment fund corpus.

Health disparities research means basic, clinical, and behavioral research on health disparity populations (including individual members and communities of such populations) that relates to health disparities, including the causes of such disparities and methods to prevent, diagnose, and treat such disparities.

Health disparity population means a population that, as determined by the Director of the NIMHD after consultation with the Director of the Agency for Healthcare Research and Quality, has a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population.

Health disparity students means students of minority health disparity populations or other health disparities populations.

Institutional endowment (IE) means the corporate or system-wide endowment fund that is the sum total of the endowment assets of all campuses and their components. This includes, but is not limited to, endowments managed by an institution's foundations/associations as well as state university systems.

Institution system-wide means all campuses and components.

Minority health conditions means, with respect to individuals who are members of minority groups, all diseases, disorders, and conditions (including with respect to mental health and substance abuse):

(1) Unique to, more serious, or more prevalent in such individuals;

(2) For which the factors of medical risk or types of medical intervention may be different for such individuals, or for which it is unknown whether such factors or types are different for such individuals; or

(3) With respect to which there has been insufficient research involving such individuals as subjects or insufficient data on such individuals.

Minority health disparities research means basic, clinical, and behavioral research on minority health conditions, including research to prevent, diagnose, and treat such conditions.

Racial and ethnic minority or minority group means American Indians (including Alaska Natives, Eskimos, and Aleuts), Asian Americans, Native Hawaiians and other Pacific Islanders, Blacks, and Hispanics. Hispanic means individuals whose origin is Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin.

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.

§ 52i.3 Who is eligible to apply?

(a) To be eligible for a grant under section 464z-3(h) of the Act an applicant:

(1) Must be a current or former center of excellence under section 736 (42 U.S.C. 293) or section 464z-4 (42 U.S.C. 285t-1) of the Act, and

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(2) Must have an institutional endowment that is equal to or less than 50 percent of the national median of endowment funds at institutions that conduct similar biomedical research and training of health professionals.

(b) To be eligible for a portion of a grant award to be expended as a research endowment under section 464z-4(f) of the Act, an applicant:

(1) Must be a designated biomedical and behavioral research institution under section 464z-4 of the Act, and

(2) Must submit those materials prescribed by the Director, NIMHD.

[80 FR 53744, Sept. 8, 2015, as amended at 89 96123, Dec. 4, 2024]

§ 52i.4 Under what conditions may an eligible institution designate a foundation as the recipient of a research endowment grant?

A number of universities and other organizations have established closely affiliated, but separately incorporated, organizations to facilitate the administration of research and other programs supported by federal funds. Such legally independent entities are often referred to as “foundations,” although this term does not necessarily appear in the name of the organization. An institution awarded an endowment grant under section 464z-3(h) of the Act or using designated grant funds for endowment purposes under section 464z-4(f) of the Act may designate a foundation associated with the institution to receive the endowment funds only for investment purposes if:

(a) The institution assures in its application that the foundation is legally authorized to receive the endowment funds and to administer the endowment funds in accordance with the regulations set forth in this part;

(b) The foundation agrees to administer the endowment funds in accordance with the regulations in this part;

(c) The institution agrees to be liable for any violation by the foundation of any applicable regulation, including any violation resulting in monetary liability; and

(d) The grantee institution has control and is responsible for the administration of the grant accounts.

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§ 52i.5 How to apply for a grant.

(a) Each institution interested in applying for a grant under section 464z-3(h) of the Act must submit an application at such time and in such form and manner as the Secretary may prescribe.

(b) An institution described in § 52i.3 that has received a grant under this part may apply for another grant under this part if:

(1)(i) The institution still meets the eligibility requirements in § 52i.3; and

(ii) The institution is in the last year of funding provided by NIH under this part; or

(2) The institution no longer has an active grant under this part from NIH.

§ 52i.6 Evaluation and award of research endowment grant applications.

All applications filed in accordance with this part and meeting the minimal eligibility requirements shall be evaluated and recommended by technical and scientific peer review. The review evaluation shall take into account, among other pertinent factors:

(a) The scientific and technical merit of the proposed project to facilitate minority health disparities research and other health disparities research;

(b) The likelihood of its producing meaningful results;

(c) The adequacy of the applicant's resources available for the project; and

(d) The adequacy of the applicant's plan for managing the endowment fund.

§ 52i.7 Grant awards.

(a) Within the limits of funds, and upon such review and recommendation as may be required by law, the Director shall award a grant to those applicants whose approved projects will in the Director's judgment best promote the purposes of this part.

(b) An institution described in § 52i.3 that receives a grant under this part or an institution described in section 464z-4(f) of the Act authorized to use grant funds for endowment purposes shall follow the spending rules under the law of the state in which the institution is located and the spending rules/policies adopted by the recipient

institution, provided that such spending rules are not inconsistent with applicable federal regulations/policies.

(c) Grants awarded under this part or grant funds designated for endowment purposes as described under section 464z-4(f) of the Act must be invested no later than 90 days after the start date of the grant.

(d) The institution, in investing the endowment fund established under this section, shall exercise the judgment and care, under the circumstances then prevailing, that a person of prudence, discretion, and intelligence would exercise in the management of such person's own affairs and avoid all appearances of conflict of interest in the management of this fund.

(e) The total amount of an endowment grant under this part or the designated amount of the grant under section 464z-4(f) of the Act must be maintained as corpus by the institution for 20 years from the end of the project period.

(f) In the case of situations in which investment conditions result in the corpus referred to in paragraph (e) of this section having a net market value less than the value of the funds at the time of their receipt, appropriate actions must be taken (*e.g.*, careful review of the investment strategy) in order to preserve the value of the endowment corpus.

(g) An institution described in § 52i.3 receiving an endowment grant under section 464z-3(h) of the Act may not simultaneously receive endowment funds under section 464z-4(f) of the Act.

(h) Consistent with section 464z-4(f) of the Act, the Director, NIMHD, may designate for a research endowment some of the funds awarded to a Center of Excellence for research education and training.

§ 52i.8 When and for what purposes may a grantee spend the endowment fund corpus?

(a) A grantee may not withdraw or spend any part of the endowment fund corpus for a total of 20 years from the end of the project period.

(b) At the end of the 20-year period, during which the endowment corpus must be maintained, the grantee institution is encouraged to preserve the

endowment fund corpus but may use the endowment fund corpus for any purpose that expands or develops the institution's minority health and/or health disparities research and/or training capacity.

§ 52i.9 How much endowment fund income may a grantee spend and for what purposes?

(a) Any endowment income realized in the initial year following the grant award under this part shall not be expended to support programmatic activities until after conclusion of the initial year of the grant.

(b) After the first year of the grant, a grantee awarded funds under this part may spend endowment income realized from funds it receives solely in accordance with the regulations of this part, the terms and conditions of the award, NIMHD policies and procedures, and the grantee's strategic plan that has been approved by the NIMHD and includes priorities for the use of the endowment fund income.

§ 52i.10 How shall a grantee calculate the amount of endowment fund income that it may withdraw and spend?

A grantee awarded funds under this part shall calculate the amount of endowment fund income that it may withdraw and spend at a particular time as follows:

(a) On each date that the grantee plans a withdrawal of endowment fund income, the grantee must determine the amount of the income by calculating the value of the fund that exceeds the endowment fund corpus.

(b) If the total value of the endowment fund exceeds the endowment fund corpus, the grantee may withdraw and spend the excess amount, *i.e.*, the endowment fund income, in accordance with § 52i.9.

§ 52i.11 What shall a grantee record and report?

A grantee awarded funds under this part shall:

(a) Maintain appropriate records in compliance with this part and other requirements as referenced in terms of the award, including documentation of:

(1) The type and amount of investments of the endowment fund;

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(2) The amount of endowment fund income and corpus;

(3) The amount and purpose of expenditures of endowment fund income; and

(4) The expenses and charges associated with the management of the endowment funds if such expenses and charges were paid from endowment fund income.

(b) Retain records in accordance with 45 CFR 75.361. The endowment fund corpus, fund income, and fund expenditures must be reported over a 20-year period, and supporting records are to be retained for 3 years after the submission of the final report to the NIMHD;

(c) Permit authorized officials the authority to conduct a review, as set forth in 45 CFR 75.364 (which states that the Department of Health and Human Services (HHS) awarding agencies, the HHS Inspector General, the U.S. Comptroller General, and any of their duly authorized representatives “have the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the awards, in order to make audits, examinations, excerpts, transcripts, or copies of such documents”); and

(d) Submit Financial Status Reports, as set forth in 45 CFR 75.341, as required by the NIMHD and in the form prescribed. A final Financial Status Report shall be required 20 years after the end of the project period.

[80 FR 53744, Sept. 8, 2015, as amended at 85 FR 72908, Nov. 16, 2020]

§ 52i.12 What happens if a grantee fails to administer the research endowment grant in accordance with applicable regulations?

(a) The Director, after giving notice and an opportunity for a hearing, may authorize the termination of a grant awarded and/or recovery of funds under this part during the 20-year period if the grantee:

(1) Withdraws or spends any part of the endowment fund corpus in violation of this part;

(2) Spends any portion of the endowment fund income not permitted to be spent in this part;

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(3) Fails to invest the endowment fund corpus in accordance with the investment standards set forth in this part;

(4) Fails to meet the requirements in § 52i.7; or

(5) Otherwise fails to comply with the terms and conditions of the award.

(b) Recovery of funds may include up to the amount of endowment awards plus any income earned.

§ 52i.13 Other HHS policies and regulations that apply.

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

(a) 2 CFR part 376—HHS Nonprocurement debarment and suspension.

(b) 42 CFR part 50, subpart D—Public Health Service grant appeals procedure.

(c) 42 CFR part 93—Public Health Service policies on research misconduct.

(d) 45 CFR part 16—Procedures of the Departmental Grant Appeals Board.

(e) 45 CFR part 46—Protection of human subjects.

(f) 45 CFR part 75—Uniform administrative requirements, cost principles, and audit requirements for HHS awards.

(g) 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.

(h) 45 CFR part 81—Practice and procedure for hearings under part 80 of this chapter.

(i) 2 CFR part 382—Requirements for drug-free workplace (financial assistance).

(j) 45 CFR part 84—Nondiscrimination on the basis of handicap in programs or activities receiving federal financial assistance.

(k) 45 CFR part 86—Nondiscrimination on the basis of sex in education programs or activities receiving federal financial assistance.

(l) 45 CFR part 91—Nondiscrimination on the basis of age in programs or activities receiving federal financial assistance from HHS.

(m) 45 CFR part 93—New restrictions on lobbying.

(n) NIH Guidelines for Research Involving Recombinant for Synthetic Nucleic Acid Molecules at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf. Further information may be obtained from the NIH Office of Science Policy (OSP) via email at NIHguidelines@od.nih.gov or the OSP website at <https://osp.od.nih.gov/>.

(o) NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>, Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html>, and the revised NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>. Further information may be obtained from the NIH Office of Research on Women's Health via email at orwhinfo@nih.gov.

(p) NIH Grants Policy Statement. The current version is located on the NIH website at <https://grants.nih.gov/policy/nihgps/index.htm>. [Note: this policy is subject to change and interested persons should contact the Division of Grants Policy in the Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research, NIH, via email at GrantsPolicy@nih.gov].

(q) Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, NIH (Revised 2015). [Note: this policy is subject to change and interested persons should contact the Office of Laboratory Animal Welfare, NIH, 6700B Rockledge Drive, Suite 2500, MSC 6910, Bethesda, MD 20892-6910 (telephone 301-496-7163, not a toll-free number), to obtain references to the current version and any amendments.

Information may be obtained also by emailing olaw@mail.nih.gov or via the OLAW website at <https://olaw.nih.gov/>.

[80 FR 53744, Sept. 8, 2015, as amended at 89 FR 96123, Dec. 4, 2024]

§ 52i.14 Additional conditions.

The Director may, with respect to any grant award, impose additional conditions prior to, or at the time of, any award when in the Director's judgment the conditions are necessary to ensure the carrying out of the purposes of the award, the interests of the public health, or the conservation of grant funds.

PART 53—GRANTS, LOANS AND LOAN GUARANTEES FOR CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND MEDICAL FACILITIES

Subparts A–K [Reserved]

Subpart L—Services for Persons Unable To Pay; Community Service; Nondiscrimination

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53.111 Services for persons unable to pay.

53.112 Nondiscrimination.

53.113 Community service.

Subpart M [Reserved]

Subpart N—Loan Guarantees and Direct Loans

53.154 Waiver of right of recovery.

53.155 Modification of loans.

53.156 Fees for modification requests.

AUTHORITY: Secs. 215, 603, 609, 621, 623, Public Health Service Act as amended, 58 Stat. 690, 78 Stat. 451 and 456, 84 Stat. 344 and 346 (42 U.S.C. 216, 291c, 291i, 291j-1 and 291j-3; 31 U.S.C. 9701).

Subparts A–K [Reserved]

Subpart L—Services for Persons Unable To Pay; Community Service; Nondiscrimination

§ 53.111 Services for persons unable to pay.

(a) *Applicability.* The provisions of this section apply to every applicant which heretofore has given or hereafter will give an assurance that it will make available a reasonable volume of services to persons unable to pay therefor but shall not apply to an applicant (1) for more than 20 years after the completion of construction of any facility with respect to which funds have