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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 52i

[Docket Number NIH-2007-0931]

RIN 0925-AA61

National Institute on Minority Health and Health Disparities Research Endowments

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Final Rule.

SUMMARY: The National Institutes of Health (NIH), through the Department of Health and Human Services (HHS), is issuing regulations governing the National Institute on Minority Health and Health Disparities (NIMHD) endowment grants awarded to section 736 and section 464z-4 Centers of Excellence to facilitate minority health disparities research and other health disparities research.

DATES: This final rule is effective [Insert the date 30 days following the date of publication].

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852; by email at MooreJ@mail.nih.gov; by fax on 301-401-0169 (not a toll free number); or by telephone on 301-496-4607 (not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 464z-3 (42 USC 285t) of the Public Health Service (PHS) Act authorizes the Director of the NIMHD to carry out a program to facilitate minority health disparities research and other health disparities research by providing research endowments to eligible centers of excellence under sections 736 and 464z-4 of the PHS Act. The program is called the NIMHD Research Endowment Program (Endowment Program). The objective of the Endowment Program is to build research and training capacity and infrastructure at eligible section 736 health professions schools (42 U.S.C. 293) and section 464z-4 biomedical and behavioral research institutions (42 U.S.C. 285t-1) to facilitate minority health and other health disparities research to close the disparity gap in the burden of illness and death experienced by racial and ethnic minority Americans and other health disparity populations. Endowment Program activities may include strengthening the research infrastructure through the renovation of facilities, purchasing of state-of-the-art instruments and equipment, and enhancing information technology; enhancing the academic environment by recruiting a diverse faculty and creating relevant courses in such topics as research methodology and health disparities as additions to the existing curriculum; enhancing recruitment of individuals currently underrepresented in the biomedical, clinical, behavioral, and social sciences; or other relevant activities.

Section 464z-4 of the PHS Act authorizes the NIMHD Director to make awards to designated biomedical and behavioral research institutions, alone or as a participant in a consortium, that meet certain criteria for the purpose of assisting the institutions in supporting programs of excellence in training for individuals who are members of minority health disparity populations or other health disparity populations. This program is called the NIMHD Centers of Excellence Program. Section 464z-4(f) of the PHS Act permits the NIMHD Director to expend a portion of such an award for research endowment.

To be eligible to apply for the Endowment Program, Centers of Excellence (funded under section 736 or section 464z-4 of the PHS Act) 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. Endowment Program applications filed by institutions meeting eligibility requirements undergo peer review by outside experts to evaluate the scientific and technical merit of the proposed activities and the adequacy of the endowment fund management plan. Reviewers use the criteria of significance, investigators, innovation, approach, and environment to determine the overall impact of the application. After receiving an Endowment Program award, a grantee must provide documentation to the NIMHD over a 20-year period regarding endowment fund activity, including investments, income, and expenditures for activities consistent with its strategic plan.

This final rule specifies the endowment research grants or endowment portion of an award to which the regulations apply (section 52i.1), the definitions (section 52i.2), who is eligible (section 52i.3) and how to apply for a grant under the program (section 52i.5), and under what conditions an eligible institution that is a recipient may transfer to a foundation a research endowment grant (section 52i.4). Additionally, the final rule specifies how endowment grant applications will be evaluated (section 52i.6), the nature of the grant awards (52i.7), how much endowment fund income a grantee may withdraw and spend and for what purpose (sections 52i.9 and 52i.10), what a grantee must record and report (section 52i.11), and when and for what purposes a grantee may spend the endowment fund corpus (section 52i.8). This final rule also specifies what happens if a grantee fails to administer the research endowment grant in accordance with applicable regulations (section 52i.12), what other HHS policies and regulations apply (section 52i.13), and what additional conditions the NIMHD Director may impose when, in the Director's judgment, the conditions are necessary (section 52i.14).

NIH announced its intentions to take this rulemaking action, through HHS, in the notice of proposed rulemaking (NPRM) titled "National Institute on Minority Health and Health Disparities Research Endowments" published in the Federal Register on June 14, 2013 (78 FR 35837-35844). In the NPRM, we provided a sixty day public comment period. The comment period expired August 13, 2013. We received a total of five comments, two of which were identical.

Three respondents, two of whom submitted identical comments, expressed general support for the regulations. One of these respondents cited the importance of

clarity regarding eligibility, the application process, and other required terms and conditions. The other two respondents discussed health disparities in the United States and research as a means to support health equity for all people in the United States. These supportive comments did not result in any necessary changes to this final rule.

One respondent stated that the Department of Health and Human Services (HHS) should require all municipalities and States that receive Federal funds from HHS for the provision of health care to notify HHS of the reasons for not considering or exploring solicited or non-solicited health disparities proposals they have received within 90 days. Since this comment is not related to any of the provisions of the Endowment Program, we did not consider the comment relevant to this rulemaking.

A fifth respondent provided comments addressing a number of issues relevant to the rulemaking, which are discussed below. This respondent requested clarification of the definition of a “Center of Excellence,” specifically, whether the act of receiving funds under section 736 or section 464z-4 is necessary for an institution to meet the definition of a Center of Excellence for purposes of the Endowment Program. The designation as a Center of Excellence for the purposes of the Endowment Program requires both receiving funding under section 736 or section 464z-4 of the Public Health Service Act and meeting certain specific nonfinancial institutional operational requirements as specified in section 736(c)(2)-(5) or section 464z-4(c)(1), respectively. The funding component of the definition in section 52i.2 is intended to clarify that an institution must be an active Center of Excellence under section 736 or section 464z-4 to be eligible for an endowment grant under this program. An institution is not eligible merely because it may be able to

satisfy the nonfinancial requirements to qualify for funding under section 736 or section 464z-4.

This respondent also requested that institutions be allowed to apply for another Endowment Program grant prior to their last year of funding. We disagree with the comment. The intent of the language in the regulation is to prevent an eligible entity with an active award from having more than a single endowment grant at any given time.

This respondent additionally inquired whether awardee institutions may now directly conduct health disparities research projects instead of capacity building for the conduct of research projects because Endowment Program applications undergo scientific peer review. This is not the case. At the NIH, the peer review of applications determines the technical and scientific merit of the proposed project. The process of peer review does not in itself convey any meaning regarding the particular activities allowed under a grant program. The Endowment Program supports the development of research infrastructure and capacity which is the underpinning of the conduct of research projects.

This respondent raised concerns regarding the scientific peer review of applications and the expertise of the members of the review groups, suggesting that applicants be able to suggest potential candidates for each review group. We disagree with the comment. One of the hallmarks of the NIH is objective, peer review of applications for financial support. The organizational units within NIH that are responsible for the review of applications take deliberate steps to ensure that the reviewers have the appropriate expertise for the applications to be reviewed. Allowing applicants to suggest potential reviewers would interfere with NIH procedures designed

to prevent possible financial and scientific conflicts of interest in the review of applications.

This respondent also expressed the belief that requiring the endowment fund corpus to be maintained for 20 years after the end of the award period is too restrictive, suggesting that awardees be given greater flexibility and allowed to expend a proportion of the endowment fund corpus earlier than 20 years. We disagree with the comment. Institutional endowments, in general, are designed to create a long-term asset capable of generating income for an extended period of time. Since the focus of the Endowment Program is to build institutional capacity and infrastructure to conduct health disparities research, any diminution of the endowment corpus in the short-term would be at odds with the goals and objectives of the Endowment Program.

This respondent requested clarity on what actions would satisfy the requirement that awardees take “appropriate actions” in cases where the investments have eroded into the value of the endowment corpus. We have not specified a strict definition for “appropriate actions” in order to allow each institution the flexibility to manage their endowment funds effectively. Certainly, a review and change of investment strategy to a more conservative approach would be an option. A temporary suspension of investment due to adverse market conditions could also be an appropriate action. We did not want to be prescriptive, but would expect actions to be reasonable and consistent with prevailing practices in the management of institutional endowments.

This respondent also inquired as to whether management costs for the endowment fund can be paid from the endowment fund itself. Section 52i.11(a) (4) of the proposed

rule provided that expenses and charges associated with the management of the endowment funds may be paid from “the grant funds.” Since the endowment fund corpus cannot be used for this purpose, section 52i.11(a)(4) has been amended to replace “the grant funds” with “endowment fund income” to clarify the issue. Awardees are expected to ensure that those costs are appropriately recorded.

This respondent suggested adding a reference to an “institution’s policies and procedures” to section 52i.9(b) regarding the expenditure of endowment fund income. We disagree with the comment. Section 52i.7(b) already specifies the need for the awardee to adhere to the institution’s spending rules and policies, provided that such spending rules are not inconsistent with applicable federal regulations and policies.

This respondent requested clarification on the timing for the filing of the final Financial Status Report under section 52.11(d). Upon approval of an application for the Endowment Program, NIMHD agrees to provide financial support for a specified project period, usually five years. Due to the unique nature of the program, it is reasonable for the long-term reporting requirement to begin at the end of the project period. To clarify the filing requirement, section 52i.11(d) has been amended to replace “date of the original award” with “end of the project period.” In addition, sections 52i.7(e) and 52i.8(a) have been amended in a consistent manner to replace “date of award” with “end of the project period.”

Finally, with regard to actions that may be taken if a grantee fails to administer the endowment in accordance to the regulations, this respondent believes that the awardee should be given an opportunity to rectify an error, unless such an error or failure

was intentional. We agree with the comment with the following qualification. The specific language in section 52i.12 is consistent with the financial stewardship responsibilities of the Federal government. The opportunity for a full and fair hearing is provided and the Director of NIMHD has discretion regarding any action to be taken depending on the circumstances of the breach in responsibilities. Limiting the range of actions available to the NIH in situations of an awardee's poor endowment fund management, even if non-intentional, would not be appropriate.

The published NPRM contained two typographical errors that have been corrected in this final rule. First, under the definition of "endowment fund" in section 52i.2, the reference to "section 464z-4" should have been "section 464z-3" of the PHS Act. Second, in the discussion of the sections of the proposed regulations that contain requirements subject to the Paperwork Reduction Act of 1995, the reference to section "52i.9" should have been specified as section "52i.9(b)". That error has been corrected in the final rule, consistent with the correct identification of section 52i.9(b) in the Reporting part of the Estimated Annual Reporting and Recordkeeping Burden table included in the NPRM and this final rule. The published NPRM contained a table on the cost burdens for reporting and recordkeeping for the NIMHD Research Endowment Program. In the final rule it has been labeled "ESTIMATED ANNUALIZED COST BURDEN TO THE RESPONDENTS FOR REPORTING AND RECORDKEEPING UNDER THE NIMHD RESEARCH ENDOWMENT PROGRAM." An additional column (designated as the 4th) was added to the table as "Average Burden per Respondents (in hours)" and columns 1, 2 3, 5, and 6 were re-titled as "Final Rule Citations," "Number of Respondents," "Number of Responses per Respondent," "Hourly

Wage Rate,” and “Total Cost Burden,” respectively. The dollar amounts in the Hourly Wage Rate column were edited to reflect the actual cost per hour for responses. In addition, the footnotes for the table were edited to be consistent with the table.

The Regulatory Flexibility Act section of the final rule has been revised to clarify that while all eligible institutions are considered small entities, the impact of the final rule will not exceed five percent of revenues of the entities.

Regulatory Impact Analyses (RIA)

We have examined the impacts of this rule as required by Executive Order 12866, Regulatory Planning and Review (September 30, 1993); Executive Order 13563, Improving Regulation and Regulatory Review (January 18, 2011); the Regulatory Flexibility Act (5 U.S.C. 601–612); the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and Executive Order 13132, Federalism (August 4, 1999).

Executive Orders 12866 and 13563

Executive Order 12866, Regulatory Planning and Review, directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in one year). Based on our analysis, we believe that the final rule does not constitute an economically significant

regulatory action. Additionally, if a regulatory action is deemed to fall within the scope of the definition of the term “significant regulatory action” contained in section 3(f) of Executive Order 12866, pre-publication review by the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB) is required. This final rule was reviewed under the criteria of Executive Order 12866 and was not deemed a “significant regulatory action.”

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Benefits

The final rule will add transparency for potential applicants regarding who is eligible and how to apply for a grant under the program, how grant applications will be evaluated, and under what conditions an eligible institution that is a recipient may transfer to a foundation a research endowment grant. Additionally, the final rule specifies the nature of the grants, how much endowment fund income a grantee may withdraw and for what purpose, what a grantee must record and report, and when and for what purposes a grantee may spend the endowment fund corpus.

This final rule also enhances compliance and effective fiduciary responsibilities for the federal government. It specifies what happens if a grantee fails to administer the research endowment grant in accordance with applicable regulations, what other HHS policies and regulations apply, and additional conditions the NIMHD Director may impose when, in the Director's judgment, the conditions are necessary. 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.

Costs

Based on the provisions of the PHS Act, approximately twelve Institutions of Higher Education (IHEs) are eligible for the NIMHD Research Endowment Program. Costs for participation can be subdivided into those associated with the application process and those required for the necessary recordkeeping. The application process includes a competitive submission, as well as noncompetitive progress report for those institutions awarded funds under the NIMHD Research Endowment Program for subsequent years within the project period. Based on estimates provided in the PHS 424 instructions, an average application should require approximately 22 hours to complete and 15 hours for a subsequent progress report, according to the PHS 2590 instructions. The contribution of various professional disciplines such as biomedical researchers, contract/grants specialists, and technical staff to the reporting and recordkeeping requirements varies. Cost estimates are based on a blended analysis of institutional salary

structure and prevailing market conditions for certain categories of personnel. In addition, fiscal year 2012 NIH salary limitations were included in the derivation of cost estimates, where applicable.

ESTIMATED ANNUALIZED COST BURDEN TO THE RESPONDENTS FOR
REPORTING AND RECORDKEEPING UNDER THE
NIMHD RESEARCH ENDOWMENT PROGRAM

Final Rule Citations	Number of Respondents ¹	Number of Responses per Respondent	Average Burden per Respondents (in hours)	Hourly Wage Rate ²	Total Cost Burden ³
Reporting:					
§52i.3(b)(2)	4	1	4	\$33.65 ⁴	\$538.40
§52i.4(a)	4	1	1	\$33.65 ⁵	\$134.60
§52i.4(c)	4	1	1	\$33.65 ⁶	\$134.60
§52i.5(a)	4	1	22	\$163.73 ⁷	\$14,408.00
§52i.9(b)	4	1	4	\$86.39 ⁸	\$1,382.24
§52i.11(b)	12	1	15	\$118.33 ⁹	\$21,300.00
§52i.11(d)	12	1	2	\$100.00 ¹⁰	\$2,400.00
Subtotal	49		\$40,297.84
Recordkeeping:					
§52i.10	12	1	2	\$200.00 ¹¹	\$4,800.00
§52i.11(a)(1)	12	1	2	\$33.65 ¹²	\$807.60
§52i.11(a)(2)	12	1	2	\$33.65 ¹³	\$807.60
§52i.11(a)(3)	12	1	2	\$33.65 ¹⁴	\$807.60
§52i.11(a)(4)	12	1	2	\$33.65 ¹⁵	\$807.60
§52i.11(b)	12	1	8	\$33.65 ¹⁶	\$3,230.40
Subtotal	18		\$11,260.80
Total			67		\$51,558.64

¹ There is currently a total of twelve institutions eligible for the NIMHD Research Endowment Program. Historically, requests for applications are solicited every three years.

² Average cost per hour.

³ Number of respondents x average burden per response x hourly wage rate.

^{4,5,6}Based on contracts/grants staff costs.

⁷Based on the contributions of the principal investigator, participating faculty, contracts/grants staff, financial investment advisors, and administrative support. Aggregate cost is \$173.73/hour.

⁸Based on principal investigator costs.

⁹Based on the contributions of the principal investigator, participating faculty, contracts/grants staff, financial investment advisors, and administrative support. Aggregate cost is \$118.33/hour.

¹⁰Based on financial analyst/auditor costs.

¹¹Based on financial investment advisor costs.

^{12,13,14,15,16}Based on contracts/grants staff costs.

Alternatives

The unique and complex nature of the NIMHD Research Endowment Program with regard to the management of endowment funds, restrictive nature of expenditures, and strict reporting provides a challenge to the necessary federal oversight. The final rule provides the guidelines for the creation of an operation structure of the institutional program. The implementation of the final rule will provide clarity to eligible and participating institutions with regard to expectations as a grantee under the program, as well as enhance the ability of the federal government to ensure the grantees are in compliance with all the applicable provisions of the statute.

The Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. For the purposes of this analysis, small entities include small business concerns as defined by the Small Business Administration, usually businesses with fewer than 500 employees. Also a nonprofit entity is defined by the Regulatory Flexibility Act as small if it is not dominant in its field, regardless of the number of employees. Eligibility requirements of the Research Endowment program, as codified in Public Law 111-148, limits the universe of potential applicants to approximately twelve institutions of higher education (IHEs). Utilizing sources of information such as local business bureaus, workforce statistics, and institution websites, a reasonable determination was made as to the approximate number of employees at eligible institutions. The range estimates are from 175-550 for the smallest institution to 3,976 for the largest and none are considered

dominant in their field. While all eligible institutions are considered small entities, the impact of the final rule will not exceed five percent of revenues of the entities.

Accordingly, the Secretary certifies that this rule will not have a significant impact on a significant number of small entities.

Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation [with base year of 1995]) in any 1 year.” The current inflation-adjusted statutory threshold is approximately \$141 million based on the Bureau of Labor Statistics inflation calculator. The Secretary certifies that this rule does not mandate any spending by state, local or tribal government in the aggregate or by the private sector. Participation in the NIMHD Research Endowment Program is voluntary and not mandated.

Executive Order 13132

Executive Order 13132, Federalism, requires federal agencies to consult with state and local government officials in the development of regulatory policies with federalism implications. The Secretary reviewed this rule as required under the Executive Order and determined that it does not have federalism implications. The Secretary certifies that this

rule will not have an effect on the states or on the distribution of power and responsibilities among the various levels of government.

Paperwork Reduction Act

This rule contains requirements that are subject to OMB approval under the Paperwork Reduction Act of 1995, as amended (44 U.S.C. chapter 35). Sections 52i.3(b)(2), 52i.4(a), 52i.4(c), 52i.5(a), 52i.9(b), 52i.11(b), and 52i.11(d) contain reporting and information collection requirements that are subject to OMB approval under the Paperwork Reduction Act. Sections 52i.10, 52i.11(a)(1), 52i.11(a)(2), 52i.11(a)(3), 52i.11(a)(4), and 52i.11(b) contain recordkeeping requirements that are subject to OMB review under the Paperwork Reduction Act. The title, program description, and respondent description of the information collection and recordkeeping requirements contained in this rule will be submitted to OMB for review. Organizations and individuals can submit comments on the information collection and recordkeeping requirements, including the burden estimates, to: (1) Seleda Perryman, Project Clearance Officer, National Institutes of Health, Rockledge Center 1, 6705 Rockledge Drive, Room 3509, Bethesda, MD 29817, telephone 301-594-7949 (not a toll-free number); and (2) the Office of Information and Regulatory Affairs, OMB, OIRA_submission@omb.eop or by fax to 202-395-6974, and mark “Attention: Desk Officer for the National Institutes of Health, Department of Health and Human Services.” After we obtain OMB approval, we will publish the OMB control number in the Federal Register.

Title: National Institute on Minority Health and Health Disparities Research Endowments.

Description: The NIMHD Research Endowment Program builds research capacity and research infrastructure in order to facilitate minority health research and research regarding other health disparity populations at eligible institutions under sections 736 and 464z-4 of the PHS Act.

Respondent Description: Institutions currently funded under Section 736 or Section 464z-4 of the Public Health Service Act (PHS Act).

ESTIMATED ANNUALIZED REPORTING AND RECORDKEEPING BURDEN
NIMHD RESEARCH ENDOWMENT PROGRAM

Citations	Number of Respondents	Number of Responses per Respondent	Average burden per Respondent (in hours)	Total Burden Hours
Reporting:				
§52i.3(b)(2).....	4	1	4	16
§52i.4(a).....	4	1	1	4
§52i.4(c).....	4	1	1	4
§52i.5(a).....	4	1	22	88
§52i.9(b).....	4	1	4	16
§52i.11(b).....	12	1	15	180
§52i.11(d).....	12	1	2	24
Subtotal.....	49	332
Recordkeeping:				
§52i.10.....	12	1	2	24
§52i.11(a)(1).....	12	1	2	24
§52i.11(a)(2).....	12	1	2	24
§52i.11(a)(3).....	12	1	2	24
§52i.11(a)(4).....	12	1	2	24
§52i.11(b).....	12	1	8	96
Subtotal.....	18	216
Total.....	67	548

Catalogue of Federal Domestic Assistance

The Catalogue of Federal Domestic Assistance-numbered program applicable to
this rule is: 93.307 - Minority Health and Health Disparities Research

List of Subjects in 42 CFR Part 52i

Grant programs—Health, Medical research.

For reasons described in the preamble, title 42 of the Code of Federal Regulations is amended by adding part 52i to read as follows.

PART 52i – NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES RESEARCH ENDOWMENT PROGRAMS

Sec.

52i.1 To what programs does this part apply?

52i.2 Definitions.

52i.3 Who is eligible to apply?

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

52i.5 How to apply for a grant.

52i.6 Evaluation and disposition of research endowment grant applications.

52i.7 Grant awards.

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

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

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

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

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

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

52i.14 Additional conditions.

Authority: 42 U.S.C. 216, 285t-285t-1.

§ 52i.1 To what programs 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 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

(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.

§ 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.

§ 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;

(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 74.53. 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 74.53(e) (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 74.52, 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.

§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;

(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 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.

(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 92--Uniform administrative requirements for grants and cooperative agreements to State, local, and tribal governments.

(n) 45 CFR part 93--New restrictions on lobbying.

(o) NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules at http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf. Further information may be obtained from the NIH Office of Biotechnology Activities via e-mail at OBA-OSP@od.nih.gov or the OBA website at <http://osp.od.nih.gov/office-biotechnology-activities>.

(p) NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>. Further information may be obtained from the NIH Office of Research on Women's Health via e-mail at ORWHINFO@mail.nih.gov or the ORWH website at <http://ORWH.od.nih.gov>.

(q) NIH Grants Policy Statement (October 1, 2013). This version is located on the NIH website at http://grants.nih.gov/grants/policy/nihgps_2013. [Note: this policy is subject to change, and interested persons should contact the Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research, NIH, 6701 Rockledge Drive, Suite 350, MSC 7974, Bethesda, MD 20892-7974 (telephone 301-435-0938 or toll-free 800-518-4726), to obtain references to the current version and any

amendments. Information may be obtained also by contacting the OPERA Division of Grants Policy via e-mail at GrantsPolicy@mail.nih.gov. Previous versions of the NIH Grants Policy Statement are archived at <http://grants.nih.gov/grants/policy/policy.htm>.]

(r) Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, NIH (Revised August 2002). [Note: this policy is subject to change, and interested persons should contact the Office of Laboratory Animal Welfare, NIH, Rockledge 1, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, MD 20892-7982 (telephone 301-594-2382, not a toll-free number), to obtain references to the current version and any amendments. Information may be obtained also via the OLAW website at <http://grants.nih.gov/grants/olaw/olaw.htm>.]

§ 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.

Dated: August 13, 2015.

Francis S. Collins, M.D., Ph.D.

Director,

National Institutes of Health

Approved: August 24, 2015.

Sylvia M. Burrell,

Secretary

Department of Health and Human Services

