

TABLE 10 TO SUBPART AAAAA OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA—Continued
 [As required in § 63.7140, you must comply with the applicable General Provisions requirements according to the following table.]

Citation	Summary of requirement	Am I subject to this requirement?	Explanations
§ 63.10(d)(5)(i)	Periodic Startup, Shutdown, Malfunction Reports.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	On and after the relevant compliance date for your source as specified in § 63.7083(g), see § 63.7131 for malfunction reporting requirements.
§ 63.10(d)(5)(ii)	Immediate Startup, Shutdown, Malfunction Reports.	Yes before the relevant compliance date for your source as specified in § 63.7083(g). No on and after the relevant compliance date for your source as specified in § 63.7083(g).	
§ 63.10(e)	Additional CMS Reports	No	See specific requirements in subpart AAAAA, see § 63.7131.
§ 63.10(f)	Waiver for Recordkeeping/Reporting.	Yes	
§ 63.11(a)–(b)	Control Device and Work Practice Requirements.	No	Flares not applicable.
§ 63.12(a)–(c)	State Authority and Delegations	Yes	
§ 63.13(a)–(c)	State/Regional Addresses	Yes	
§ 63.14(a)–(b)	Incorporation by Reference	No	
§ 63.15(a)–(b)	Availability of Information and Confidentiality.	Yes	
§ 63.16	Performance Track Provisions	Yes	

[FR Doc. 2024–27874 Filed 12–3–24; 8:45 am]
 BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 52i

[Docket No. NIH–2022–0001]

RIN 0925–AA70

National Institute on Minority Health and Health Disparities Research Endowment Programs

AGENCY: National Institutes of Health, HHS.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or Department), through the National Institutes of Health (NIH), is amending the regulation governing the National Institute on Minority Health and Health Disparities (NIMHD) Research Endowment Programs (REP) to update the heading of the regulation to reflect the new name of the program, the eligibility requirements for the program to indicate the new expanded eligibility for research endowment awards that is mandated by statute, the heading of one section of the regulation, and certain references to regulations and policies cited in the regulation that apply to program grant awards.

DATES: This final rule is effective January 3, 2025.

FOR FURTHER INFORMATION CONTACT:

Daniel Hernandez, NIH Regulations Officer, Office of Management Assessment, NIH, Rockledge 1, 6705 Rockledge Drive, Suite 601, Room 601–T, Bethesda, MD 20817, MSC 7901, by email at dhernandez@mail.nih.gov, or by telephone at 301–435–3343 (not a toll-free number). For program information contact: Dr. Nathan Stinson, Director, Division of Community Health and Population Sciences, NIMHD, by email stinsonn@nih.gov, or telephone 301–594–8704. Information concerning the requirements, application deadline dates, and an on-line application for NIMHD REP awards may be obtained from the NIMHD via <https://www.nimhd.nih.gov/programs/extramural/research-endowment.html>.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Mandate

On March 18, 2022, the President signed into law the John Lewis NIMHD Research Endowment Revitalization Act of 2021, Public Law (Pub. L.) 117–104. Section 2 of this law amended section 464z–3(h) of the Public Health Service (PHS) Act, as amended (42 U.S.C. 285t(h)) by revising program eligibility requirements to include eligible current or former Health Resources and Services Administration (HRSA) centers of excellence under section 736 of the PHS Act and eligible current or former NIMHD centers of excellence under section 464z–4 of the PHS Act.

The program was originally authorized under the Minority Health and Health Disparities Research and Education Act of 2000 (Pub. L. 106–525). The law provided annual funding for up to five years to the endowments of active eligible HRSA centers of excellence. In 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) expanded eligibility to include active eligible NIMHD centers of excellence. Public Law 117–104, enacted in 2022, expanded the eligibility for NIMHD Research Endowment Program awards to eligible current or former HRSA and NIMHD centers of excellence. Endowment funds must be invested and maintained for at least 20 years after the award period ends.

The objective of the program and its awards is to build research and training capacity and infrastructure at eligible HRSA or NIMHD centers of excellence to facilitate minority health and other health disparities research and to close the disparity gap in the burden of illness and death experienced by racial and ethnic minority Americans and other health disparity populations. 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 faculty and creating relevant training courses focused on minority health and health

disparities, in addition to the existing curriculum, such as research methodology and health disparities; and/or other relevant activities. The expansion of eligibility for the program, recently renamed the *John Lewis* NIMHD Research Endowment Program, to include eligible current or former HRSA and NIMHD centers of excellence will serve to expand the national capacity of academic institutions to conduct research to improve minority health and reduce health disparities.

Implementation of Public Law 117–104 necessitates HHS, through NIH, to update the regulation codified at 42 CFR part 52i that governs the program. Specifically, paragraph (a)(1) of § 52i.3 “Who is eligible to apply?” needs to be updated to specify the expanded statutory eligibility for program awards, such that eligible current or former centers of excellence under section 736 (42 U.S.C. 293) or section 464z–4 (42 U.S.C. 285t–1) of the PHS Act, respectively, may now apply.

Additionally, following enactment of Public Law 117–104, NIMHD changed the name of the program from the NIMHD Research Endowment Program to the *John Lewis* NIMHD Research Endowment Program to reflect the honor that the United States Congress bestowed upon John Lewis by naming the legislation expanding eligibility for the program after him. John Robert Lewis served in the U.S. House of Representatives, representing Georgia’s 5th Congressional District from 1987 until his death in 2020 with longstanding commitment to improving minority health and health disparities. Consequently, the heading of the regulation that governs the program must be amended to reflect the new name of the program.

Other aspects of the regulation also need to be updated. In the heading for § 52i.1 and in the accompanying Table of Contents reference to § 52i.1, the word “programs” in “To what programs does this part apply?” needs to be changed to “program” to correctly indicate that there is only one program to which part 52i applies, not multiple programs as the current heading incorrectly indicates.

Additionally, in § 52i.13, “Other HHS policies and regulations that apply”, there are outdated references to several regulations and policies with URLs that are not operational. The current references in paragraph (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 the certain grants and agreements with

states, local governments and Indian tribal governments”, and paragraph (m) “45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State, local and tribal governments” are outdated and must be revised. The current references in paragraphs (o) concerning NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, (p) concerning NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, (q) concerning NIH Grants Policy Statement, and (r) concerning Public Health Service Policy on Humane Care and Use of Laboratory Animals contain outdated information and, in some cases, the URLs are not operational. These paragraphs need to be updated.

Previously, HHS issued a direct final rule on November 16, 2020 (85 FR 72899–72912) amending certain regulations as part of its Regulatory Clean Up Initiative to make miscellaneous corrections, including correcting references to other regulations, misspellings, and other typographical errors. These corrections included several changes in 42 CFR part 52i. However, the revisions that now are necessary in § 52i.13 were not included in the direct final rule.

HHS announced its intentions to initiate this rulemaking action in the notice of proposed rulemaking (NPRM) titled “National Institute on Minority Health and Health Disparities Research Endowment Programs” that was published in the **Federal Register** on October 4, 2023 (88 FR 68553). The NPRM provided a sixty-day public comment period. The comment period ended December 4, 2023.

In the NPRM, we proposed to amend the Code of Federal Regulations by revising the heading for 42 CFR part 52i to read “Part 52i—*John Lewis* NIMHD Research Endowment Program” to reflect the new name of the program, the *John Lewis* NIMHD Research Endowment Program.

We proposed to amend the heading for § 52i.1 “To what programs does this part apply?” by removing the word “programs” and adding the word “program” in its place to indicate that there is only one program, the *John Lewis* NIMHD Research Endowment Program, to which part 52i applies.

Additionally, we proposed to amend § 52i.3 “Who is eligible to apply?” by revising paragraph (a)(1) to read as follows: “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”.

We further proposed to amend § 52i.13 “Other HHS policies and regulations that apply” by:

- (1) Revising current paragraph (f),
- (2) Removing current paragraph (m), and redesignating current paragraph (n) as new paragraph (m),
- (3) Redesignating current paragraph (o) as new paragraph (n) and revising it,
- (4) Redesignating current paragraph (p) as new paragraph (o) and revising it,
- (5) Redesignating current paragraph (q) as new paragraph (p) and revising it,
- (6) Redesignating current paragraph (r) as new paragraph (q) and revising it, and
- (7) Removing paragraph (r).

We stated in the NPRM that making these changes was necessary to implement Public Law 117–104 and would ensure the regulation is up to date. We added that the rule, when finalized, would add transparency for potential applicants regarding who is eligible to apply for a grant under the *John Lewis* NIMHD Research Endowment Program.

II. Summary of Public Comments

We received five comments in response to the NPRM. One of the commenters agreed with the proposed rule, noting that implementation of Public Law 117–104 will lead to an increase in eligible applicants and will have a positive impact in addressing minority health disparities.

A second commenter stated that the proposed rule was acceptable because it is more in line with the new name of the program recognized after the late John Lewis, and because the program aims to build more training and research capacity to reduce disparities in minority health treatment, the program eligibility requirements should mirror such to become more inclusive for minority applicants to apply.

A third commenter thought the proposed rule should be expanded to create new medical schools at Historically Black Colleges and Universities (HBCUs), noting that it missed the opportunity to expand the number of Black doctors. Additionally, the commenter noted that there are only six Black medical schools in the country, and that with major health disparities in the Black community, it is essential to expand the number of providers who are committed to serving that population. The commenter noted that out of 10 states with the highest Black populations, only three have HBCUs with medical schools. The commenter reiterated his belief that the proposed rule also should expand to include establishing medical schools in

these states at HBCUs to expand the provider pool.

We appreciate the commenter taking the time to extensively comment on the proposed rule and we acknowledge the importance of addressing health disparities through a diverse healthcare workforce. The *John Lewis* NIMHD Research Endowment Program provides funding for endowments to invest in research infrastructure and training capacity at eligible institutions. The comment advocating expanding the criteria beyond the scope of the Program was determined to exceed the stated limited purpose of the proposed rule and beyond the authority provided by the Program's authorizing statute.

A fourth commenter stated the regulation should not be amended. No rationale was provided.

Finally, a fifth comment was deemed not pertinent to the proposed rule, and thus is not discussed here.

After considering these comments, we did not adopt any suggested changes.

III. Regulatory Impact Analysis

We examined the impacts of this rule under Executive Order 12866, Regulatory Planning and Review; Executive Order 13563, Improving Regulation and Regulatory Review; Executive Order 14094, Modernizing Regulatory Review; Executive Order 13132, Federalism; the Regulatory Flexibility Act (5 U.S.C. 601–612); and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094

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). The Executive Order 14094 entitled “Modernizing Regulatory Review” amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or

communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is “not significant” under section 3(f) and does not meet the criteria set forth in 5 U.S.C. 804(2) under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Thus, an RIA is unnecessary.

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. We reviewed the rulemaking as required under the Order and determined that it does not have any federalism implications. This rulemaking will not have effect on the states or on the distribution of power and responsibilities among the various levels of government.

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 this analysis, small entities include small business concerns as defined by the Small Business Administration (SBA), usually businesses with fewer than 500 employees. Also, a not-for-profit entity is defined by the Regulatory Flexibility Act as small if it is independently owned and operated and not dominant in its field, regardless of the number of employees. Eligibility requirements of the *John Lewis* NIMHD Research Endowment Program, as codified in Public Law 117–104, limits the universe of potential applicants to an estimated maximum of 42 institutions of higher education (IHEs). Utilizing sources of information such as local business bureaus, workforce statistics, and

institution websites, a reasonable determination can be made from the approximate number of employees of eligible institutions. The range estimates are from 51–200 employees for the smallest institution to 10,600 employees for the largest. While most eligible institutions are considered small entities, the impact of this rulemaking will not exceed 5 percent of revenues of the entities. Accordingly, the Secretary certifies this rulemaking 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 agencies to prepare a written statement, to include an assessment of anticipated costs and benefits, before proposing any rule that includes a Federal mandate that may result in the expenditure by State, local and tribal governments or more, in the aggregate or by the private sector, of \$100,000,000 [adjusted annually for inflation (with base year 1995)] in any 1 year. The current inflation-adjusted statutory threshold is approximately \$183 million based on the Bureau of Labor Statistics inflation calculator. The Secretary certifies that this rulemaking does not mandate any spending by State, local, or tribal government in the aggregate or by the private sector. Participation in the *John Lewis* NIMHD Research Endowment Program is voluntary and not mandated.

Paperwork Reduction Act

This rule does not contain any new information collection requirements that are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). However, part 52i contains information collection and recordkeeping requirements. Specifically, §§ 52i.3(b)(2), 52i.4(a), 52i.4(c), 52i.5(a), 52i.9(b), 52i.11(b), and 52i.11(d) of part 52i contain reporting requirements, and §§ 52i.10, 52i.11(a)(1), 52i.11(a)(2), 52i.11(a)(3), 52i.11(a)(4), and 52i.11(b) of part 52i contain recordkeeping requirements.

These reporting and recordkeeping requirements are addressed in the grant application forms per OMB Control Number 0925–0001 and 0925–0002, which address the instructions for SF–424 and SF–2590. There is nothing that needs to be done regarding the burden associated with these requirements in part 52i, because it is already estimated based upon the data that is collected through the various eRA systems that grantees use. The approvals under OMB Control Number 0925–0001 and OMB

Control Number 0925–0002 expire January 2026.

We do not expect an increase in average burden per respondent because of the enactment of Public Law 117–104 and the new expanded eligibility for research endowment awards that it mandates, or implementation of the

program’s new expanded eligibility requirements through this proposed rule. Also, we do not expect a change in the number of responses per respondent. However, there likely will be a change in the number of respondents from 4 to 22, and the total

of burden hours will need to be adjusted based on the number of respondents.

We estimate the annualized burden to the respondents for reporting and recordkeeping under the *John Lewis* NIMHD Research Endowment Program as:

ESTIMATED ANNUALIZED BURDEN TO THE RESPONDENTS FOR REPORTING AND RECORDKEEPING UNDER THE *John Lewis* NIMHD RESEARCH ENDOWMENT PROGRAM

Citations	Number of respondents ¹	Number of responses per respondent	Average burden per respondents (in hours)	Total burden hours ²
Reporting				
§ 52i.3(b)(2)	22	1	4	88
§ 52i.4(a)	22	1	1	22
§ 52i.4(c)	22	1	1	22
§ 52i.5(a)	22	1	22	484
§ 52i.9(b)	22	1	4	88
§ 52i.11(b)	6	1	15	90
§ 52i.11(d)	6	1	2	12
Subtotal			49	806
Recordkeeping				
§ 52i.10	6	1	2	12
§ 52i.11(a)(1)	6	1	2	12
§ 52i.11(a)(2)	6	1	2	12
§ 52i.11(a)(3)	6	1	2	12
§ 52i.11(a)(4)	6	1	2	12
§ 52i.11(b)	6	1	8	48
Subtotal			67	108
Total		158		914

¹ There is currently a total of 42 institutions eligible for the *John Lewis* NIMHD Research Endowment Program, we estimate 22 institutions will apply. Historically, requests for applications are solicited every 5 years.

² Annual number of respondents × annual number of responses × average burden per response.

When it is time to renew pre/post grant application forms, NIH will reach out to community members in a 2–3-year timeframe to determine if burden is the same, or if it has increased or

decreased and provide additional input. The burden has already been accounted for at this time.

We estimate the current annualized cost burden to the respondents for

reporting and recordkeeping under the *John Lewis* NIMHD Endowment Program as:

ESTIMATED ANNUALIZED COST BURDEN TO THE RESPONDENTS FOR REPORTING AND RECORDKEEPING UNDER THE *John Lewis* 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 burden ³
Reporting					
§ 52i.3(b)(2)	22	1	4	⁴ 39.72	\$3,495.10
§ 52i.4(a)	22	1	1	39.72	873.78
§ 52i.4(c)	22	1	1	39.72	873.78
§ 52i.5(a)	22	1	22	⁵ 193.25	93,533.25
§ 52i.9(b)	22	1	4	⁶ 101.97	8,973.02
§ 52i.11(b)	6	1	15	⁷ 139.66	12,569.84
§ 52i.11(d)	6	1	2	⁸ 118.03	1,416.36
Subtotal			49		121,735.13
Recordkeeping					
§ 52i.10	6	1	2	⁹ 236.06	2,832.72

ESTIMATED ANNUALIZED COST BURDEN TO THE RESPONDENTS FOR REPORTING AND RECORDKEEPING UNDER THE *John Lewis* NIMHD RESEARCH ENDOWMENT PROGRAM—Continued

Final rule citations	Number of respondents ¹	Number of responses per respondent	Average burden per respondents (in hours)	Hourly wage rate ²	Total burden ³
§ 52i.11(a)(1)	6	1	2	39.72	476.61
§ 52i.11(a)(2)	6	1	2	39.72	476.61
§ 52i.11(a)(3)	6	1	2	39.72	476.61
§ 52i.11(a)(4)	6	1	2	39.72	476.61
§ 52i.11(b)	6	1	8	39.72	1,906.42
Subtotal			18	39.72	6,645.56
Total			67		128,380.69

¹ There is currently a total of 42 institutions eligible for the *John Lewis* NIMHD Research Endowment Program, we estimate 22 institutions will apply. Historically, requests for applications are solicited every 5 years.
² Average cost per hour.
³ Number of respondents × average burden per response × hourly wage rate.
⁴ Based on contracts/grants staff costs.
⁵ Based on the contributions of the principal investigator, participating faculty, contracts/grants staff, financial investment advisors, and administrative support. Aggregate cost is \$205.05/hour.
⁶ Based on principal investigator costs.
⁷ Based on the contributions of the principal investigator, participating faculty, contracts/grants staff, financial investment advisors, and administrative support. Aggregate cost is \$139.66/hour.
⁸ Based on financial analyst/auditor costs.
⁹ Based on financial investment advisor costs.

Federal Assistance Listings

The Federal Assistance Listings numbered program affected by this rulemaking is:
 93.307—Minority Health and Health Disparities

List of Subjects in 42 CFR Part 52i

Grant programs—Health, Medical research.
 For reasons described in the preamble, the Department of Health and Human Services amends 42 CFR part 52i as set forth below:

PART 52i—JOHN LEWIS NIMHD RESEARCH ENDOWMENT PROGRAM

- 1. The authority citation for part 52i continues to read as follows:
Authority: 42 U.S.C. 216, 285t–285t–1.
- 2. The heading to part 52i is revised to read as set forth above.
- 3. The heading to § 52i.1 is revised to read as follows:

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

- * * * * *
- 4. Section 52i.3 is amended by revising paragraph (a)(1) to read as follows:

§ 52i.3 Who is eligible to apply?

- (a) * * *
- (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
- * * * * *

■ 5. Section 52i.13 is amended by revising paragraphs (f), and (m) through (q) and removing paragraph (r) to read as follows:

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

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

Xavier Becerra,
 Secretary, Department of Health and Human Services.

[FR Doc. 2024–28082 Filed 12–3–24; 8:45 am]

BILLING CODE 4140–01–P