

*Information Collection Request Title:* HIV Quality Measures (HIVQM) Module OMB No. 0906–0022—Extension.

*Abstract:* The HRSA Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people with HIV. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people diagnosed with HIV in the United States. Nearly two-thirds of clients live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities.<sup>1</sup>

RWHAP Parts A, B, C, and D recipients and sub recipients must follow legislative requirements for the establishment of clinical quality management programs to assess the extent to which their HIV services are consistent with the most recent Department of Health and Human Services Clinical Treatment guidelines. In support of these requirements, HRSA created the HIV Quality Measures (HIVQM) Module as an online tool to assist recipients in meeting the clinical quality management program requirement by allowing recipients to input data for the HRSA performance measures. HRSA maintains over 40 performance measures across the

following categories: (1) core, (2) all ages, (3) adolescent/adult, (4) HIV-infected children, (5) HIV-exposed children, (6) medical case management, (7) oral health, (8) AIDS Drug Assistance Program, and (9) systems. The HIVQM Module also supports the requirement imposed by the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Health and Human Service Award (45 CFR 75.301) that recipients relate financial data to performance accomplishments of their federal awards. The HIVQM Module helps recipients set goals and monitor performance measures and quality improvement projects. The use of the HIVQM Module is voluntary for RWHAP recipients but strongly encouraged.

*Need and Proposed Use of the Information:* The HIVQM Module supports recipients and sub-recipients in their clinical quality management programs, performance measurement, service delivery, and monitoring of client health outcomes and quality HIV services. The HIVQM Module is accessible via the RWHAP Services Report, an existing online portal that RWHAP recipients use for required data collection of their services. Recipients may enter performance measures data into the HIVQM Module four times a year and then generate reports to assess their performance. Recipients have the option to enter data for specific populations for a subset of performance measures based on age, gender, race/ethnicity, and risk factor. Recipients

may also compare their performance against other recipients in their state, region, and nationally. Additionally, recipients can choose the performance measures they want to monitor and enter data accordingly. For recipients and sub-recipients participating in the Centers for Medicare & Medicaid Incentive Programs, such as the Medicare Promoting Interoperability Program and the Merit-based Incentive Payment System, the HIVQM Module may be used to monitor the HRSA measures that qualify and comply with the requirements to receive incentives from these programs.

*Likely Respondents:* RWHAP Part A, Part B, Part C, and Part D recipients and their sub-recipients.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

#### TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
HIVQM Report .....	2,063	4	8,252	1	8,252
	2,063	.....	8,252	.....	8,252

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

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**BILLING CODE 4165–15–P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### National Institutes of Health

#### Proposed Collection; 60-Day Comment Request; Post-Award Reporting Requirements Including Research Performance Progress Report Collection (OD)

**AGENCY:** National Institutes of Health.

**ACTION:** Notice.

<sup>1</sup> HRSA. Ryan White HIV/AIDS Program Data Report, 2020.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301-435-0941 or email your request, including your address to [ProjectClearanceBranch@mail.nih.gov](mailto:ProjectClearanceBranch@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who

are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Proposed Collection Title:* Public Health Service (PHS) Post-award Reporting Requirements Revision, OMB 0925-0002, Expiration Date 9/30/2024, Office of the Director (OD), National Institutes of Health (NIH).

*Need and Use of Information Collection:* Starting in January 2023, NIH will require applicants and recipients to submit and address Data Management and Sharing Plans within the SF424 Research and Related (R&R) application and the Research Performance Progress Report (RPPR) in accordance with the final NIH Policy for Data Management and Sharing (DMS Policy) to promote the management and sharing of scientific data generated from NIH-funded or conducted research. The application and progress report forms will be updated to align with this requirement. NIH will also be updating the PHS 2271 Statement of Appointment form so that trainees appointed to institutional Ruth L. Kirschstein National Service Research Awards (NSRA) can document when they receive support for childcare costs. The RPPR is required to be used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR required the maintenance of dual reporting processes for a period of time. Continued use of the PHS Non-competing Continuation Progress Report (PHS 2590), exists for a small group of grantees. This collection also includes other PHS post-award reporting requirements: PHS 416-7 NSRA Termination Notice, PHS 2271 Statement of Appointment, 6031-1

NSRA Annual Payback Activities Certification, HHS 568 Final Invention Statement and Certification, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. The PHS 416-7, 2271, and 6031-1 is used by NSRA recipients to activate, terminate, and provide for payback of a NSRA. Closeout of an award requires a Final Invention Statement (HHS 568) and Final Progress Report. iEdison allows grantees and Federal agencies to meet statutory requirements for reporting inventions and patents. The PHS 3734 serves as the official record of grantee relinquishment of a PHS award when an award is transferred from one grantee institution to another. Pre-award reporting requirements are simultaneously consolidated under 0925-0001 and the changes to the collection here are related. Clinical trials are complex and challenging research activities. Oversight systems and tools are critical for NIH to ensure participant safety, data integrity, and accountability of the use of public funds. NIH has been engaged in a multi-year effort to examine how clinical trials are supported and the level of oversight needed. The collection of more structured information in the PHS applications and pre-award reporting requirements as well as continued monitoring and update during the post-award reporting requirements will facilitate NIH's oversight of clinical trials. In addition, some of the data reported in the RPPR will ultimately be accessible to investigators to update certain sections of forms when registering or reporting their trials with [ClinicalTrials.gov](https://clinicaltrials.gov). *Frequency of response:* Applicants may submit applications for published receipt dates. For NSRA awards, fellowships are activated, and trainees appointed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 532,249.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Information collection forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
<b>REPORTING</b>				
PHS 416-7 .....	12,580	1	30/60	6,290
PHS 6031-1 .....	1,778	1	20/60	593
PHS 568 .....	11,180	1	5/60	932
iEdison .....	5,697	1	15/60	1,424
PHS 2271 .....	22,035	1	15/60	5,509
PHS 2590 .....	243	1	18	4,374
RPPR—Core Data .....	32,098	1	8	256,784
Biosketch (Part of RPPR) .....	2,544	1	2	5,088

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Information collection forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Data Tables (Part of RPPR) .....	758	1	4	3,032
Trainee Diversity Report (Part of RPPR) .....	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information .....	6,420	1	3	25,680
Publication Reporting .....	97,023	3	5/60	24,256
Final RPPR—Core Data .....	18,000	1	10	180,000
Data Tables (Part of Final RPPR) .....	758	1	4	3,032
Trainee Diversity Report (Part of Final RPPR) .....	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information (Part of Final RPPR) ....	3,600	1	4	14,400
PHS 3734 .....	479	1	30/60	240
Reporting Burden Total .....				531,874

## RECORDKEEPING

SBIR/STTR Life Cycle Certification .....	1,500	1	15/60	375
Grand Total .....		411,699		532,249

Dated: June 1, 2022.

**Tara A. Schwetz,**  
Acting Principal Deputy Director, National  
Institutes of Health.

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Endocrinology and Metabolism.

*Date:* July 1, 2022.

*Time:* 10:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Baskaran Thyagarajan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 800B, Bethesda, MD 20892, (301) 867-5309, [thyagarajanb2@csr.nih.gov](mailto:thyagarajanb2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-20-281: Fertility Status as a Marker for Overall Health.

*Date:* July 12, 2022.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Anthony Wing Sang Chan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 809K, Bethesda, MD 20892, (301) 435-5000, [chana2@csr.nih.gov](mailto:chana2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Auditory System, Cognition and Memory.

*Date:* July 12, 2022.

*Time:* 10:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Pablo M. Blazquez Gamez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435-1042, [pablo.blazquezgamez@nih.gov](mailto:pablo.blazquezgamez@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Innate Immunity and Inflammation.

*Date:* July 13, 2022.

*Time:* 9:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Aftab A. Ansari, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, (301) 237-9931, [ansaria@csr.nih.gov](mailto:ansaria@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Infectious Disease and Immunology B.

*Date:* July 14-15, 2022.

*Time:* 9:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Uma Basavanna, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-827-1398, [uma.basavanna@nih.gov](mailto:uma.basavanna@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Cancer Immunology and Immunotherapy.

*Date:* July 14-15, 2022.

*Time:* 9:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7806, Bethesda, MD 20892, 301-451-4467, [howardz@mail.nih.gov](mailto:howardz@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Special Topics in Biomaterials, Biointerfaces, Gene and Drug Delivery.

*Date:* July 15, 2022.

*Time:* 10:00 a.m. to 9:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).