

and pharmacodynamics of nicotine exposure in users; (4) abuse liability and dependence; (5) short and long-term health effects in users; (6) considerations for high risk or vulnerable populations; and (7) human factors. Additional information related to workshop presentations and discussion topics, including specific questions to be addressed at the workshop, can be found at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm>.

Dated: December 22, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought 42 CFR Part 50 Subpart F and Responsible Prospective Contractors 45 CFR Part 94 (OD)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director (OD), 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.

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.

To submit comments and for further information: 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. Kathy Hancock, Assistant Grants Compliance Officer, Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration (OPERA), 6705 Rockledge Drive, Room 3523, Bethesda, MD 20892, or call non-toll-free number (301) 435-1962, or Email your request, including your address to: FCOICompliance@

mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

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

Proposed Collection: Title: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought 42 CFR part 50 Subpart F and Responsible Prospective Contractors 45 CFR part 94 OMB# 0925-0417, Expiration Date: 02/2015, EXTENSION, National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: This is a request for OMB Approval for an extension of the information collection and recordkeeping requirements contained in the final rule 42 CFR part 50, subpart F and 45 CFR part 94. The purpose of these regulations is to promote objectivity in research by requiring institutions to establish standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator financial conflicts of interest.

OMB approval is requested for an extension of 3 years. There are operating costs and/or maintenance costs per response. The total estimated annualized burden hours are 676,130.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent based on applicable section of regulation	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Reporting				
Initial Reports under 42 CFR 50.605(b)(1) and (b)(3) or 45 CFR 94.5(b)(1) and (b)(3) from Awardee Institutions	950	1	2	1,900
Subsequent Reports under 42 CFR 50.605(a)(3)(iii) and (b)(2) or 45 CFR 94.5(a)(iii) and (b)(2) from Awardee Institutions	50	1	2	100
Mitigation Reports under 45 CFR 94.5(a)(3)(iii) and (b)(2) from Awardee Institutions	5	1	2	10
Annual Report under 42 CFR 50.605(b)(4) or 45 CFR 94.5(b)(4) from Awardee Institution	950	1	1	950
Subsequent Reports under 42 CFR 60.606(a) or 45 CFR 94.6(a) from Awardee Institution	20	1	10	200
Record Keeping				
Under 42 CFR 50.604(i) or 45 CFR 94.4(i) from Awardee Institutions	2,000	1	4	8,000
Disclosure				
Under 42 CFR 50.604(a) or 45 CFR 94.4(a) for Investigators	3,000	1	81	243,000
Under 42 CFR 50.604(b) or 45 CFR 94.4(b) for Investigators	38,000	1	30/60	19,000
Under 42 CFR 50.604(b) or 45 CFR 94.4(b) for Institutions	2,000	1	6	12,000

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent based on applicable section of regulation	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Under 42 CFR 50.604(c)(1) or 45 CFR 94(c)(1) from Sub-recipients	500	1	1	500
Under 42 CFR 50.604(d) or 45 CFR 94.4(d) Institutions	3,000	1	1	3,000
Under 42 CFR 50.604(e)(1) or 45 CFR 94.4(e)(1) for Investigators	38,000	1	4	152,000
Under 42 CFR 50.604(e)(2) or 45 CFR 94.4(e)(2) for Investigators	38,000	1	1	38,000
Under 42 CFR 50.604(e)(3) or 45 CFR 94.4(e)(3) for Investigators	950	1	30/60	475
Under 42 CFR 50.604(f) or 45 CFR 94.4(f) for Institutions	2,000	1	1	2,000
Under 42 CFR 50.605(a)(1) or 45 CFR 94.5(a)(1) for Institutions	2,000	1	82	164,000
Under 42 CFR 50.605(a)(3) or 45 CFR 94.5(a)(3) for Institutions	500	1	3	1,500
Under 42 CFR 50.605(a)(3)(i) or 45 CFR 94.5(a)(3)(i) for Institutions	50	1	80	4,000
Under 42 CFR 50.605(a)(3)(ii) or 45 CFR 94.5(a)(3)(ii) for Institutions	50	1	80	4,000
Under 42 CFR 50.605(a)(3)(iii) or 45 CFR 94.5(a)(3)(iii) for Institutions	50	1	1	50
Under 42 CFR 50.605(a)(4) or 45 CFR 94.5(a)(4) for Institutions	950	1	12	11,400
Under 42 CFR 50.605(a)(5) or 45 CFR 94.5(a)(5) for Institutions	2,000	1	5	10,000
Under 42 CFR 50.606(c) or 45 CFR 94.6(c) for Institutions	50	1	30/60	45

Dated: December 17, 2014.

Lawrence Tabak,

Deputy Director, Office of the Director, NIH.

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BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NINR)

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the National Institute of Nursing Research has submitted a Generic Information Collection Request (Generic ICR): “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery” to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Rebecca Hawes, Division of Science Policy and Public Liaison, NINR, NIH, Democracy One, 6701 Democracy Blvd., Suite 710, Bethesda, MD 20892, by phone at (301) 594-0791 or email your request, including your address to: hawesr@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

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

Proposed Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, 0925-0653, Expiration Date 3/31/2015, EXTENSION, National Institutes of Health (NIH), National Institute of Nursing Research (NINR).

Need and Use of Information Collection: There are no changes being requested for this submission. The information collection activity will continue to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration’s commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Improving agency programs requires ongoing assessment of service delivery, by which we mean systematic review of the operation of a program compared to a set of explicit or implicit standards, as a means of contributing to the

continuous improvement of the program. The Agency will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current services and make improvements in service delivery based on feedback. The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency’s services will be unavailable.

NINR will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;