agents; concepts and priorities for the development and implementation of standards for other classes of respirators; and research work to identify stimulant materials for use as CBRN test surrogates for respirator research and development efforts.

NIOSH and its standards development partners, U.S. Army Soldier and Biological Chemical Command (SBCCOM) and the National Institute for Standards and Technology (NIST), will present information to attendees concerning the development of the concepts and priorities being considered for the development of standards for the various classes of respirators. Participants will be given an opportunity to ask questions and to present individual comments that they may wish to have considered. Interested participants may obtain a copy of the APR CBRN standard concept paper from the NIOSH contact identified below, or from the NIOSH National Personal Protective Technology Laboratory Web site, address: http://www.cdc.gov/niosh/npptl.

Recent acts of terrorism have created an urgent awareness of domestic security and preparedness issues. Municipal, states, and federal responder groups, particularly those in locations considered potential targets, have been developing and modifying response and consequence management plans. Since the World Trade Center and anthrax incidents, most emergency response agencies have operated with a heightened appreciation of the potential scope and sustained resources requirements for coping with such events. The federal Interagency Board for Equipment Standardization and Interoperability (IAB) has worked to identify personal protective equipment that is already available on the market for responders’ use. The IAB has identified the development of standards or guidelines for respiratory protection equipment as a top priority. NIOSH, NIST, National Fire Protection Association and the Occupational Safety and Health Administration have entered into a Memorandum of Understanding defining each agency or organization’s role in developing, establishing and enforcing standards or guidelines for responders’ respiratory protective devices. NIST has initiated Interagency Agreements with NIOSH and SBCCOM to aid in the development of appropriate protection standards or guidelines. NIOSH has the lead in developing standards or guidelines to test, evaluate and approve respirators.

NIOSH, SBCCOM, and NIST hosted a public meeting April 17 and 18, 2001, and presented their progress in assessing respiratory protection needs of responders to chemical, biological, radiological and nuclear incidents. The methods or models for developing hazard and exposure estimates, and the status in evaluating test methods and performance standards that may be applicable as future chemical biological, radiological, and nuclear respirator standards or guidelines were discussed at that meeting. On December 28, 2001, NIOSH announced standards for the evaluation and approval of Self Contained Breathing Apparatus to protect emergency responders against chemical, biological, radiological, and nuclear agents. NIOSH and SBCCOM are in the process of developing chemical, biological, radiological and nuclear respiratory protection standards and guidelines for full facepiece Air-Purifying Respirators (APR) as well as other classes of respirators. The June 18 and 19, 2002 public meeting will provide an update on those activities.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Szalajda, NIOSH, PO Box 18070, 626 Cochran Mill Road, Pittsburgh, PA 15236, telephone 412/386–6627, fax 412/386–6747 and/or e-mail: respcent@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

DATED: May 24, 2002.

John Burckhardt,
Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02–13639 Filed 5–30–02; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1209–N]

Medicare Program; Notice of Modification of Beneficiary Assessment Requirements for Skilled Nursing Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: As part of the Secretary’s Regulatory Reform Initiative, this notice offers to skilled nursing facilities (SNFs) the option of using a modified, shorter version of the minimum data set (MDS) to satisfy the Medicare SNF payment and quality requirements. The Medicare SNF prospective payment system rates are based on the assignment of beneficiaries to case-mix classification groups. Beneficiaries are assigned to groups based on the information collected by the SNF staff and recorded on the MDS. The quality measures are also derived from the information recorded on the MDS and all of those items are included in this modified, shorter version. This shorter version of the MDS will reduce the burden on SNFs by approximately one-half, which may result in saving a significant amount of time that could be made available to staff for the provision of beneficiary care. We are offering to SNF providers the option of using the shorter version of the MDS to meet the requirements to receive payment for Part A SNF stays.

DATES: This notice is effective July 1, 2002.

FOR FURTHER INFORMATION CONTACT: Dana Burley (410) 786–4547.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (the Secretary) has made regulatory reform a priority. To further this goal, the Secretary established an Advisory Committee on Regulatory Reform to provide advice on potential administrative and regulatory changes that could reduce burdens and costs while maintaining or enhancing effectiveness and access to health care. In order to fulfill its mandate, among other activities, the committee has held public hearings, heard testimony from providers and beneficiary groups, and visited a skilled nursing facility (SNF) to examine the regulatory burdens imposed on SNFs.

During the course of its deliberations, the Advisory Committee examined the minimum data set (MDS) and identified almost two dozen MDS areas for review. While affirming the critical contribution of the MDS to quality, the committee has identified some MDS issues that relate to the size of the instrument and the need to focus data collection on payment, outcome, and survey purposes. The modifications announced in this notice address one of the issues identified in the course of the activities undertaken by the Advisory Committee.

In this notice, we are announcing the option of using a shorter MDS developed for use by providers to assess Medicare beneficiaries for purposes of

II. Background

The Minimum Data Set (MDS) is a uniform, standardized instrument used under the Medicare SNF prospective payment system to: (1) obtain the necessary data for determining the payment rate for a Part A SNF stay; and (2) assess the quality of the care provided by the SNF. The MDS is also used to assign beneficiaries to case-mix classification groups. The Medicare SNF prospective payment system rates are based on the assignment of beneficiaries to case-mix classification groups. Beneficiaries are assigned to groups basen...
the SNF prospective payment system (PPS) assessment requirements during their Part A covered SNF stays. This is one step in our ongoing effort to streamline our regulatory requirements for providers who participate in the Medicare program and for our beneficiaries.

The current Medicare assessment requirements are based on section 4432(a) of the Balanced Budget Act of 1997 (BBA), that amended section 1888(e) of the Social Security Act (the Act), which mandated implementation of a Medicare skilled nursing facility (SNF) prospective payment system. Section 1888(e)(4) of the Act provides the basis for establishing the per diem Federal payment rates applied under the PPS and sets forth the formula for the rates, including the data on which they are based. In addition, this section of the Act requires annual adjustments to the PPS rates based on geographic variation and SNF case-mix and prescribes the methodology for updating the rates in future years.

The PPS case-mix adjustments are derived from the clinical information collected by providers about Medicare Part A covered beneficiaries during their SNF stays, using the minimum data set (MDS). As a result of a mandate contained in the nursing home reform legislation in the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), a uniform MDS was required as a part of the comprehensive resident assessment for all certified long-term care facilities. The provisions of OBRA '87 require that certified long-term care facilities collect information concerning all residents to support care planning activities. Comprehensive assessments, using the MDS, are required at admission (no later than 14 days following admission), annually, and upon a significant change in a resident's condition. In addition, quarterly reviews of each resident are required. A shorter version of the MDS has been developed for these quarterly assessments.

With implementation of the SNF PPS, providers were required to perform MDS assessments of all beneficiaries in Medicare Part A covered stays on days 5, 14, 30, 60, and 90 of their Medicare covered stays. The assessments required for the SNF PPS are in addition to those required by the OBRA '87, although there is often overlap in the timing of the required assessments so that one assessment may be used to satisfy both the OBRA '87 and SNF PPS requirements.

At the time of implementation of the SNF PPS, we were aware that some refinements to the payment system might be required as we learned more during the national operational period. However, because of what we learned from the demonstration, and in order to have full national level data on Medicare beneficiaries (including their resource use requirements), we did not believe that a shorter version of the MDS was appropriate at that time.

The SNF PPS has now been in place for more than 2 full years and we believe that it is now feasible to offer providers the option of using a shorter version of the MDS. There is no regulatory impediment to our making such an offer, as an option, a shorter version of the MDS for purposes of Medicare payment and quality monitoring. We find that the information that we have collected from the full MDS since implementation of the Medicare SNF PPS, which is stored in the National MDS Repository, in addition to the continued collection of information from both the full MDS and the optional shorter version, are adequate to support payment, program integrity, quality monitoring, and provider and beneficiary educational activities.

The OBRA '87 requirements remain unchanged. Only those MDS assessments that are performed solely for the purpose of satisfying the Medicare SNF PPS assessment requirements are affected by this decision to offer a shorter version of the MDS. For those Medicare SNF PPS assessments, SNFs may, at their option, use a shorter version of the MDS, the Medicare PPS Assessment Form, Version 2002 (MPAF). This shorter version is available for provider use beginning July 1, 2002 and is currently available on the SNF PPS web site at www.hcfa.gov/medicare/SNFPPS.htm. The MPAF contains all of the MDS items needed to calculate the beneficiary's RUG–III classification and Quality Indicators.

The nursing home reform provisions of the OBRA '87 established the MDS as key to the process for ensuring the quality of care for nursing home residents. All current assessments address quality of care, although the OBRA '87-required 14-day and 90-day assessments are intended primarily for quality evaluation and care planning support. The shorter version of the MDS offered in this notice in no way undermines the important quality assurance and care planning support functions of the process. We remain committed to the ongoing collection of information, as specified in the OBRA '87, as a cornerstone of the provision of high quality care for all long term care facility residents.

In addition to the quality provisions of OBRA '87, the Secretary has initiated a Nursing Home Quality Initiative, designed to assess the quality of care provided by SNFs. As an integral part of this initiative, we are making information about local nursing homes available to members of the communities in which they operate. The first step in this process, to pilot test quality measures and publish those scores, is underway in 6 States (Florida, Maryland, Ohio, Rhode Island, Washington, and Colorado). Quality measurement and ensuring that high quality care is provided to all residents in certified nursing facilities remains a priority and will be the focus of ongoing research activity. Therefore, the MPAF was designed so that it includes all of the data elements required to derive all of the current quality measures.

Due to our strong interest in quality assurance and our ongoing research efforts related to outcome measures for quality, as well as MDS accuracy, new payment and classification systems and assessment instruments across post-acute care settings, it is certain that, over time, the scope and content of items included on all MDS assessment instruments will change. For example, we are planning to modify the full MDS in order to simplify some items and update others, according to clinical practices. This modification will be the MDS 3.0, which we expect to complete in 2004. Similarly, we are engaged in a significant effort to develop tools to help providers educate staff and assure the accuracy of their MDS assessments. This work is being performed through a Program Safeguard contract and includes monitoring of other aspects of nursing facility practices, in addition to the MDS accuracy studies. We will also work on developing systems by which we can monitor MDS assessments on a national level.

II. Development of the MPAF

Development of this new, shorter version of the MDS was based on the RUG–III Quarterly, Optional Version, 1997 Update. This version of the MDS contains almost all of the items needed to calculate the Medicare RUG–III case-mix classification groups and is already part of the State standard MDS systems. However, the RUG–III Quarterly does not include Sections AA8b and T of the MDS that are essential for the PPS, the risk adjustment items necessary for calculating the Quality Indicators, certain items required for the Quality Medical Review function of the Peer Review Organizations (PROs), or items we believed may be useful for refinements to the payment system.

The addition of items to the RUG–III Quarterly from the MDS to satisfy the
requirements of ongoing Medicare payment policy research, PRO tasks, and quality monitoring resulted in an assessment form that is somewhat longer than the RUG–III Quarterly, but still significantly shorter than the full MDS.

III. Optional Use of the MPAF

The MPAF will be available for use July 1, 2002. Providers may choose to use this shorter version of the MDS to satisfy the Medicare SNF PPS requirements for assessments at days 5, 14, 30, 60, and 90 of Medicare Part A covered stays. The requirement for an Other Medicare Required Assessment (OMRA) 8 to 10 days after cessation of all rehabilitation therapy may also be satisfied by using the MPAF.

With the implementation of the SNF PPS, compliance with the OBRA ’87 requirement for an Initial Admission Assessment by the 14th day and the Medicare SNF PPS requirements for an assessment 5 and 14 has been met routinely by performing one assessment to meet both requirements. This has been a fairly seamless combination of requirements, since the SNF PPS requirements, before the implementation of this optional MPAF, called for a full MDS assessment and the Initial Admission Assessment also required the full MDS, as well as additional care planning activities. It will still be possible to use one assessment to comply with both the OBRA ’87 clinical rules and the Medicare SNF PPS assessment requirements. The provider will be required to meet the more rigorous standard (comprehensive assessment to comply with the requirement for an initial admission assessment) and may use that assessment to comply with the lesser Medicare requirement.

IV. Implementation

The items on the MPAF are the same as they appear on the full MDS. We have not altered wording, instructions for completion, or numbering in development of the MPAF. For example, MDS item I1m (hip fracture) on the full MDS is also item I1m (hip fracture) on the MPAF, even though on the MPAF this item is followed by I1r (aphasia), rather than I1n (missing limb), which has been removed from this shorter version of the assessment form. Since our intent in providing this revised, shortened version of the MDS is to alleviate burden on providers, we have maintained the ordering and numbering system of the MDS items. We believe that this will minimize confusion for clinical staff who are used to the item numbering as it exists on the full version of the MDS and support ease of use of the revised version.

With the implementation of the MPAF, the burden on SNF providers will also be lessened. Once the MPAF is implemented, we will no longer require a Medicare SNF PPS assessment to be performed using the full MDS. Rather, only the new MPAF will be required. The MPAF will be essentially a RUG–III 1997 Update Quarterly assessment form with items added to allow evaluation of SNF quality of care.

Beginning July 1, 2002, facilities will have the option to (1) submit Medicare SNF PPS records using only the MPAF items, or (2) continue to submit Medicare SNF PPS records using the full MDS. The standard MDS system used by the States will accept either type of record as valid. The standard system will validate and store only the set of MPAF items. Additional items will be ignored by the system. Some providers may wish to continue to send a full MDS assessment to avoid revising MDS data entry software. If that is the case, no submission errors or warnings will result.

When a Medicare SNF PPS assessment would be coupled with a required clinical assessment (for example, a 14-day Medicare SNF PPS assessment combined with an initial admission assessment) we will require the MDS record to include all of the MPAF items plus any additional items required by the clinical assessment, in order to satisfy both sets of assessment requirements.

If any Medicare SNF PPS assessment is combined with a comprehensive assessment (initial assessment, annual assessment, significant change in status assessment, or significant correction of prior full MDS assessment), we will require the record submitted to include all comprehensive assessment items. When a Medicare SNF PPS assessment is coupled with a quarterly assessment or a significant correction of a prior quarterly assessment, we will require the record submitted to include all MPAF items and any additional items required by the State’s quarterly assessment. In States using our standard minimum quarterly or standard RUG–III quarterly assessment, the MPAF items will include all items on the quarterly assessments, and only the MPAF will be required. In States that require additional quarterly items, not included on the MPAF, those additional items will be required to be included on a combined Medicare SNF PPS and quarterly assessment record. For example, in the 7 States that require a full MDS assessment as the quarterly assessment, a record combining a Medicare SNF PPS assessment and a quarterly assessment will have to include all of the full MDS items.

V. Collection of Information Requirements

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA), the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper functions of the agency’s functions; (2) the accuracy of our estimate of the information collection 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the PRA, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB’s regulations at 5 CFR Part 1320. We cannot reasonably comply with the normal clearance procedures because the MPAF will be effective on July 1, 2002.

We are requesting OMB review and approval of this collection within 15 days of the date of this publication, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below within 14 days of this publication. During this 180-day period, we will publish a separate Federal Register notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements.

Summary: SNFs are required to submit the resident assessment data described at 42 CFR 483.20, in the manner necessary to administer the payment rate methodology described in § 413.337. Pursuant to sections 4204(b)
and 4214(d) of OBRA ’87, the current requirements related to the submission and retention of resident assessment data are not subject to the PRA. However, the requirement to maintain performance of patient assessment data for days 5, 30, and 60 following admission, necessary to administer the payment rate methodology described in §413.337, is subject to the PRA, and is approved by OMB under approval number 0938–0739, with a current expiration date of April 30, 2003. Since we are now making the collection and submission of certain MDS items optional, as referenced in this notice, we are soliciting comments on the optional data elements and burden reduction associated with the revised reporting requirements.

We have submitted a copy of this notice to OMB for its review of the information collection requirements.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access our web site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, telephone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office at (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, within 14 days of the publication of this notice:

Centers for Medicare & Medicaid Services, Office of Information Services, Standards and Security Group, Division of CMS Enterprise Standards, 7500 Security Boulevard, Room N2–14–26, Baltimore, MD 21244–1850, Fax: (410) 786–0262

VI. Regulatory Impact Analysis

We have examined the impact of this notice as required by Executive Order 12866, directs agencies to assess 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 effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This notice is not significant as defined in Title 5, United States Code, section 804(2).

The UMRA also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure in any year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million or more. This notice will have no consequential effect on State, local, or tribal governments. We believe the private sector cost of this notice falls below these thresholds as well.

Executive Order 13132 (effective November 2, 1999) establishes certain requirements that an agency must meet when it promulgates regulations that impose substantial direct compliance costs on State and local governments, preempt State law, or otherwise have Federalism implications. As stated above, this notice will have no consequential effect on State and local governments.

The RFA requires agencies to analyze options for regulatory relief on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most SNFs and most other providers and suppliers are small entities, either by virtue of their nonprofit status or by having revenues of $10 million or less annually. For purposes of the RFA, all States and tribal governments are not considered to be small entities, nor are intermediaries or carriers. Individuals are also not included in the definition of a small entity. The provisions of this notice, to make available a shorter version of the MDS to meet Medicare payment requirements, creates no additional regulatory burden on small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This notice only applies to those few small rural hospitals that have distinct-part skilled nursing units. For those few providers, the option provided by this notice decreases the regulatory burden and requires no action by the provider.

We do not believe that there will be any negative effect on either the quality of care delivered, or on our ability to monitor the quality of that care, as a result of decreasing the amount of clinical information that will be collected for Medicare beneficiaries during their SNF stays. The MPAF includes all of the assessment items required for the resident assessment instrument by the OBRA ’87, as well as all of the items to support current quality monitoring. Further, the Secretary’s Advisory Committee on Regulatory Reform strongly favored a reduction of the amount of data collection required from nursing facilities, an indication of the expected reception by the public of this new version of the MDS.

Facilities may be concerned about making changes to their computer systems in order to be able to enter and transmit the MPAF electronically. We note that there is no requirement for facilities to integrate this version of the MDS into their systems. The facility has complete discretion regarding when, and if, it chooses to begin use of this assessment form. The RAVEN grouper and MDS transmission software that is available at no cost from our web site at www.hcfa.gov/medicare/mds20/mdsoftw.htm will support the use of the MPAF. Also, the State systems will accept the MPAF beginning July 1, 2002.

We estimate that the MPAF will require approximately half as much time to complete as the full MDS. Completion of the MPAF will require approximately 45 minutes, compared to approximately 90 minutes required to complete the MDS currently in use. Depending on the SNF’s level of Medicare participation, use of the MPAF may result in saving a significant amount of time that could be made available to staff for the provision of beneficiary care.

VII. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the Federal Register to provide a period for public comment before the provisions of a notice such as this take effect. We can waive this procedure, however, if we find good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of
the finding and its reasons in the notice issued.

We find that it is unnecessary and contrary to the public interest to undertake notice and comment rulemaking because this notice merely provides SNFs with the option to use a shorter version of the MDS to satisfy the Medicare assessment requirements, thus, lessening the burden on the SNF providers. There is no change to the current practices of SNF providers in completing the MDS resident assessment instrument. Therefore, for good cause, we waive prior notice and comment procedures.

(Proposed Information Collection Request)

The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Proposed Collection**

Title: Special Volunteer and Guest Researcher Assignment.

Type of Information Collection Request: Extension of OMB No. 0925–0177: 07/31/02.

Need and Use of Information Collection: Form NIH–590 records, names, address, employer, education, and other information on prospective Special volunteers and Guest Researchers, and is used by the responsible NIH approving official to determine the individual’s qualifications and eligibility for such assignments. The form is the only official record of approved assignments.

Affected Public: Individuals or households.

Type of Respondents: Guest Researchers, and Special Volunteer candidates.

Estimated Number of Respondents: 1,630.

Estimated Number of Responses Per Respondent: 1.

Average Burden Hours Per Response: .1.

Estimated Total Annual Burden Hours Requested: 163. There are no Capitol Costs, Operating Costs, and/or Maintenance Costs to report.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; Comment Request; Special Volunteer and Guest Researcher Assignment**

**SUMMARY:** Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on January 31, 2002, (Volume 67, Number 21) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Requests for Comments**

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 agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and the clarity of 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.

**DIRECT comments to:** Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH.