TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.29; Termination of MUMS designation	2	1	2	1	2
516.30; Requirements for annual reports	15	5	75	2	150
516.36; Insufficient quantities	1	1	1	3	3
Total					1,362

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the current investigational new animal drug/new animal drug application reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: November 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28598 Filed 11–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Data Collection To Understand How NIH Programs Apply Methodologies To Improve Their Research Programs (MIRP)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 9, 2013, page 55084 and allowed 60-days for public comment. One comment was received. However, the issues addressed in the comment were not related to the information collection proposed, and will not be considered in the finalization process. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Allergy and Infectious Diseases (NIAID), 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Ms. Dione Washington, Strategic Planning and Evaluation Branch, OSPIDA, NIAID, NIH, 6610 Rockledge Dr., Rm 2501, Bethesda, MD 20892–6620, or Email your request, including your address to *washingtondi@niaid.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Data collection to understand how NIH programs apply methodologies to improve their research programs (MIRP), 0925–NEW, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH).

Need and Use of Information Collection: In this submission, NIAID is requesting an OMB generic clearance for formative research activities relating to the collection of data to assist the Institute in understanding the usefulness of a range of methodologies that are employed to increase organizational effectiveness. The Office of Management and Budget (OMB) and Office of Science and Technology Policy (OSTP) have instructed agencies to apply rigorous strategy management principles to ensure resources are directed at high-priority programs and avoid duplication of effort. A key aspect to ensuring resources dedicated to these programs are applied efficiently and effectively is to understand how NIH research programs apply methodologies to improve their organizational effectiveness. The degree of an organization's effectiveness is commonly recognized to be influenced by many factors. These can include the clarity of its purpose and strategy, how it allocates and structures its work, the processes used to carry out operations, the way technologies are used to support work, the people involved and their skills and abilities, the way relationships are managed with partners and stakeholders, and how leadership functions, particularly in terms of its ability to ensure that all the other components are aligned in supporting work towards the mission. Many methodologies are commonly employed in all sectors, including government, with the goal of increasing organizational effectiveness. Some examples of those used widely are strategic planning and strategy management, total quality management, change management, organizational assessment and intervention, organizational design, process improvement, leadership development, performance management, and workforce training and professional development, among others. There are many models and approaches to each of these methodologies. Each one can be implemented in a wide range of ways. Reflection on and learning from methodologies that have been used and the ways in which they have been employed is critical to continually ensuring that government functions effectively.

The primary use for information gathered through voluntary survey pilot testing, surveys, focus groups, interviews, and collaborative data interpretation meetings to understand the use of strategy management in research programs supported by the NIH. The information will improve approaches to implementing strategic management, which will lead to more efficient use of resources. Results gathered in these data will be used to

enhance implementation of methodologies to improve organizational effectiveness. The main goal of this information is to improve program outcomes and increase the efficiency of resource utilization. The knowledge gained from these collections will be used to strengthen the planning, implementation, and monitoring of NIH research programs, as well as to strengthen strategy management in NIH research programs.

The questions asked, and the data to be collected are rooted in established business-based paradigms but specifically adapted for use (and relevance) in a biomedical research environment, in order to discern: 1) Factors that enhance (or inhibit) organizational effectiveness in research programs; 2) utility and acceptance of these kinds of efforts among biomedical researchers and research stakeholders. The results from this formative research project will inform quality improvement activities in several areas, including goal setting, capability and resource evaluation, operational efficiency, and performance monitoring. Utilized data collection methodologies will be administered in a manner that minimizes public information collection burden. These include, but are not limited to, surveys, focus groups, and/or cognitive interviews. Separate and distinct generic clearances are requested to facilitate the efficiency of submission and review of these projects as required by the OMB Office of Information and Regulatory Affairs

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4775.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Pilot Test	Science professional, researchers, institutional officials, network leadership, program administrators, and research site staff..	900	1	45/60	675
Survey		2500	1	30/60	1250
Interview		1000	1	90/60	1500
Focus group		375	1	2/60	750
Data interpretation meeting with stakeholders.		150	1	4/60	600

Dated: November 21, 2013.

Brandie Taylor,

Project Clearance Liaison, Chief, Evaluation Section, OPSIDA, NIAID, NIH.

[FR Doc. 2013–28636 Filed 11–27–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Device for Vascular Dilation

Description of Technology: The invention is an enhanced vascular dilator that eliminates the vascular injury caused by the size mismatch between vascular introducer sheaths and vascular dilators, as the two are advanced into a blood vessel. The invention provides a ''shoulder'' to match the diameter of the introducer sheath so that there is a smooth transition, without size mismatch, between the dilator and the introducer sheath. The invention allows the dilator to be withdrawn in segments from the introducer sheath. This is especially valuable to reduce vascular injury when using large-bore introducer sheaths for interventional procedures including transcatheter valves and endografts.

Potential Commercial Applications:

- Caval access.
- Vascular access.

Competitive Advantages: Non-perforating.

Development Stage: Prototype.

Inventors: Robert Lederman (NHLBI), Ozgur Kocaturk (NHLBI), Adam Greenbaum (Henry Ford Hospital).

Intellectual Property: HHS Reference No. E–759–2013/0—US Provisional Patent Application 61/890,961 filed 15 October 2013.

Licensing Contact: Michael Shmilovich; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Heart, Lung, and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize interventional catheter-based procedures to reduce vascular injury. For collaboration opportunities, please contact Peg Koelble at *koelblep@nhlbi.nih.gov.*

Her2 Monoclonal Antibodies, Antibody Drug Conjugates, and Site Specific Antibody Conjugate Methods

Description of Technology: Antibody drug conjugates (ADC) can demonstrate high efficacy as cancer therapeutics, however, much more can be done to improve their efficacy and safety profile. Site-specific antibody drug conjugation is a promising way to do this.

The scientists at the NIH have identified a fully human monoclonal antibody, m860, that binds to cell surface-associated Her2 with affinity