III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be provided within 30 days of publication of this document (see **DATES**) by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm.* FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the cell, tissue, and gene transfer products manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16038 Filed 7–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Evaluation of the NIH Academic Research Enhancement Award (NIH 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 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 to address 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: Michelle M. Timmerman, Ph.D., Director, AREA Program, Office of the Director, National Institutes of Health, 6705 Rockledge Drive, Bethesda, Maryland 20892; or call non-toll-free number 301–402–0672; or email your request, including your address to *michelle.timmerman@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: Evaluation of the NIH Academic Research Enhancement Award, 0925-New, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: The Academic Research Enhancement Award (AREA) Program is a grant mechanism spanning most of the Institutes and Centers (ICs) of the National Institutes of Health (NIH). The AREA program was established by Congress in 1985 to provide support to scientists at public and private colleges and universities that receive relatively small amounts of NIH funding. The purpose of the program is to support meritorious research, expose undergraduate and graduate students to research, and strengthen the research environment of the institutions receiving the grants. In the past three years alone, the federal government has awarded approximately 78 million dollars annually in AREA grants. The evaluation will allow the NIH and Congress to assess the extent to which the AREA program is meeting its goals and make recommendations so that this significant investment of public funds may be used as effectively as possible.

The evaluation will utilize the NIH's archived data on grants, institutions, Principal Investigators (PIs), and students funded with AREA monies. The evaluation will collect new data about (1) the quantity and quality of student participation in AREA projects, (2) records of PIs' subsequent funding histories, (3) applicants' experiences with the application process, (4) PIs' experiences implementing AREA Program objectives, and (5) the impact of AREA Program research participation on student career paths and outcomes.

The results of the evaluation will indicate the extent to which the AREA Program is meeting its goals of supporting meritorious research, strengthening the research environment at institutions of higher education that are not research intensive, and recruiting and training subsequent generations of the United States' biomedical scientist workforce. Intended audiences include the United States Congress, staff at NIH ICs that make AREA awards, and staff of the NIHOD.

OMB approval is requested for one year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 629.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Principal Investigator Survey	480	1	45/60	360
Awardee Semi-Structured Interview	50	1	45/60	38
Student Survey	301	1	30/60	151

ESTIMATES OF ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Applicant Survey	240	1	20/60	80

Dated: July 2, 2014.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2014–16072 Filed 7–8–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: AAV Mediated Aquaporin-1 Gene Transfer To Treat Sjögren's Syndrome

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to Milo, LLC, a company having its headquarters in Cleveland, Ohio, to practice the inventions embodied in U.S. Provisional Patent Application No. 61/695,753, filed 20 April 2011 (HHS Ref. No. E–139–2011/1–US–01]), and PCT Patent Application No. PCT/US13/57632, filed 30 August 2013 (HHS Ref. No. E–139–2011/1–PCT–02), entitled ''AAV Mediated Aquaporin-1 Gene Transfer to Treat Sjögren's Syndrome.'' The patent rights in these inventions have been assigned to or exclusively licensed to the Government of the United States of America. The territory of the prospective license may be worldwide and the field of use may be limited to: ''the use of the Licensed Patent Rights, limited to AAV mediated aquaporin-1, for the treatment of Sjögren's syndrome in humans.''

Upon the expiration or termination of the Start-Up Exclusive Evaluation Option License Agreement, Milo will have the exclusive right to execute a Start-up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-Up Exclusive Evaluation Option License Agreement.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 24, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Vince Contreras, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4711; Facsimile: (301) 402–0220; Email: *vince.contreras@nih.gov.* A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The subject technology includes methods of treating Sjögren's syndrome by using recombinant adeno associated virus (rAAV) serotypes as vectors to deliver a gene that expresses AQP1. Aquaporin-1 is a pore protein that selectively channels water molecules across the cell membrane. Using animal models that mimic the dry mouth symptoms (xerostomia) of Sjögren's, it was discovered that there was restoration of fluid movement upon expression of AQP1. This potentially represents a long-term treatment for restoring exocrine gland function in Sjögren's patients where salivary gland activity is significantly reduced.

The prospective Start-Up Exclusive Evaluation Option License Agreement will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective Start-Up Exclusive Evaluation Option License Agreement and a subsequent Start-Up Exclusive Patent License Agreement may be granted unless the NIH receives, within fifteen (15) days from the date of this published notice, written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are filed in response to this Notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement. Comments and objections submitted in response to this Notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 7, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–16030 Filed 7–8–14; 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