

Dated: March 11, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2014-06999 Filed 3-28-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-Day Comment Request: Generic Clearance To Support the Safe to Sleep Campaign at the Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development, 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 December 30, 2013, pages 79472–79473 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 Institute of Child Health and Human Development, 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.

**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: Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496–1877 or Email your request, including your address to *glavins@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

**Proposed Collection:** Generic Clearance to Support the Safe to Sleep Campaign at the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD), 0925—NEW, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

**Need and Use of Information Collection:** This is a request for a new generic clearance that would be used for submissions specific to the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Safe to Sleep (STS) public education campaign. Submissions for the STS campaign will be used to assess the understanding and reach of STS campaign materials and messages, and to monitor and improve campaign activities such as training workshops and overall implementation. The purpose of this information collection is to monitor and modify campaign activities, to plan future campaign activities, to develop messages and materials, and to develop distribution and outreach strategies that are effective at communicating their message to bring about the intended response, awareness, and/or behavioral change for the target audiences. This generic clearance will enable the NICHD to: (1) More efficiently assess the implementation of campaign activities; (2) better understand the target audiences' knowledge, attitudes, and beliefs toward STS messages and materials; (3) better understand how the campaign activities have influenced the target audiences' behaviors and practices; and (4) monitor and improve activities such as trainings, and material/message development. Having a way to gather feedback on the

STS campaign activities is critical to assessing the reach and effect of campaign efforts. Data collected for the campaign can inform where future STS campaign resources can produce the most meaningful results.

Data collected for the STS campaign generic clearance will be used by a number of audiences, including STS campaign staff, NICHD leadership, STS campaign collaborators, Federal Sudden and Unexpected Infant Deaths (SUID)/Sudden Infant Death Syndrome (SIDS) Workgroup members, SUID/SIDS stakeholders, clinical and maternal/child health professionals, parents and caretakers, and the general public. These audiences may use the information collections to: (1) Develop new campaign messages, materials, and/or training curricula; (2) monitor and improve campaign activities; (3) make decisions about campaign activities; (4) inform current campaign activities; and (5) inform and/or change practices and behaviors of program participants.

Examples of the types of information collections that could be included under this generic clearance include: *Focus groups and in-depth interviews* with parents/caregivers and/or health professionals to get feedback on distribution and outreach activities, and/or campaign messages; and *Surveys* with parents/caregivers and/or health professionals to: (1) Assess the usefulness of the new STS campaign materials, including print and on-line materials and a video, (2) track outreach experiences of program participants, (3) assess training participants' changes in knowledge related to safe infant sleep behavior and implementation of outreach methods taught, and (4) assess program participants' resource needs.

The sub-studies for this generic will be small scale, designed to obtain results frequently and quickly to guide campaign development and implementation, inform campaign direction, and be used internally for campaign management purposes. NICHD's current scope and capacity for STS generic sub-studies is non-existent and this request would fill this gap.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 3,000.

#### Estimated Annualized Burden Hours

TABLE 1—ESTIMATES FOR ANNUAL BURDEN HOURS

Type of data collection instrument	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Focus Groups .....	500	1	1	500
Pre/Post Test .....	2,500	1	15/60	625
Survey .....	2,500	1	15/60	625
Interview .....	500	1	1	500
Tracking/Feedback Form .....	1,500	1	30/60	750
Total .....	7,500	.....	.....	3,000

Dated: March 21, 2014.

**Sarah L. Glavin,**

*Deputy Director, Office of Science Policy, Analysis, and Communications, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.*

[FR Doc. 2014-07105 Filed 3-28-14; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License: The Development of a Single Domain Human Anti-Mesothelin Monoclonal Antibody for the Treatment of Human Cancers**

**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, Department of Health and Human Services, is contemplating the grant of an exclusive start-up option license to practice the inventions embodied in U.S. Patent Application 61/706,396 entitled “Mesothelin Antibodies and Methods for Eliciting Potent Antitumor Activity” [HHS Ref. E-236-2012/0-US-01], PCT Application PCT/US2013/059883 entitled “Mesothelin Antibodies and Methods for Eliciting Potent Antitumor Activity” [HHS Ref. E-236-2012/0-PCT-02], and all related continuing and foreign patents/patent applications for the technology family, to H2Bio, Inc. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive start-up option licensed territory may be worldwide, and the field of use may be limited to:

The use of the monoclonal antibody SD1 (and glycoengineered variants thereof) as an antibody therapy for the treatment of mesothelioma, pancreatic cancer, ovarian cancer and lung adenocarcinoma. The

Licensed Field of Use explicitly excludes the use of the antibody in the form of an immunoconjugate, including, but not limited to, immunotoxins.

Upon the expiration or termination of the exclusive start-up option license, H2Bio, Inc. will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive start-up option license with no greater field of use and territory than granted in the exclusive start-up option license.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 15, 2014 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; Email: [lambertsond@mail.nih.gov](mailto:lambertsond@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** This invention concerns a monoclonal antibody and methods of using the antibody for the treatment of mesothelin-expressing cancers, including mesothelioma, lung cancer, ovarian cancer and pancreatic cancer. The specific antibody covered by this technology is designated SD1, which is a single domain, fully human monoclonal antibody against mesothelin.

Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer cells. The SD1 antibody can selectively bind to these cancer cells and induce cell death while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive start-up option license 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 exclusive start-up option license may be granted unless the NIH receives 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 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive start-up option license. Comments and objections submitted 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: March 27, 2014.

**Richard U. Rodriguez,**

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

[FR Doc. 2014-07022 Filed 3-28-14; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License: Multivalent Vaccines for Rabies Virus and Ebola and Marburg (Filoviruses)**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a an exclusive license to practice the following invention as embodied in the following patent applications: E-032-2011/0, Blaney *et al.*, “Multivalent Vaccines for Rabies Virus and Filoviruses,” U.S. Patent Application Number 61/439,046, filed