

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Resources and Services Administration****Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received within 30 days of this notice.

**ADDRESSES:** Submit your comments, including the Information Collection

Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* HRSA Telehealth Outcome Measures. OMB No. 0915-0311—Revision.

*Abstract:* In order to help carry out its mission, the Office for the Advancement of Telehealth (OAT) created a set of performance measures that grantees can use to evaluate the effectiveness of their services programs and monitor their progress through the use of performance reporting data.

*Need and Proposed Use of the Information:* As required by the Government Performance and Results Act of 1993 (GPRA), all federal agencies must develop strategic plans describing their overall goal and objectives. The Office of Rural Health Policy, Office for the Advancement of Telehealth (OAT), has worked with its grantees to develop performance measures to be used to

evaluate and monitor the progress of the grantees. Grantee goals are to: Improve access to needed services; reduce rural practitioner isolation; improve health system productivity and efficiency; and improve patient outcomes. In each of these categories, specific indicators were designed to be reported through a performance monitoring Web site.

*Likely Respondents:* Telehealth Network Grantees.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS**

| Form name                                            | Number of respondents | Number of responses per respondent | Total responses | Average Burden per Response (in hours) | Total burden hours |
|------------------------------------------------------|-----------------------|------------------------------------|-----------------|----------------------------------------|--------------------|
| Performance improvement measurement system (PIMS) .. | 700                   | 2                                  | 1400            | 7                                      | 9,800              |

Dated: November 18, 2013.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2013-28203 Filed 11-22-13; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Prospective Grant of Exclusive License: Development of Chitosan/IL-12 Conjugate as Immunotherapeutic Products for 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 patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Scion Cardio-vascular (“Scion”) located in Miami, FL, USA.

*Intellectual Property*

1. U.S. Provisional Patent Application No. 60/846,481; filed September 22, 2006 entitled “Methods and Compositions for the Treatment of Cancer” [HHS Ref. No. E-311-2006/0-US-01];

2. International Patent Application No. PCT/US2007/020540 filed September 21, 2007 entitled “Compositions And Methods For Chitosan Enhanced Immune Response” [HHS Ref. No. E-311-2006/1-PCT-01];

3. European Patent Application No. 07838692.7 filed September 21, 2007 entitled “Compositions And Methods For Chitosan Enhanced Immune Response” [HHS Ref. No. E-311-2006/1-EP-02]; and

4. U.S. Patent Application No. 12/442,483 filed March 23, 2009 entitled

“Compositions And Methods For Chitosan Enhanced Immune Response” [HHS Ref. No. E-311-2006/1-US-03].

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use will be limited to the use of Licensed Patent Rights for development of Chitosan/IL-12 conjugates as immunotherapeutic products for human cancers. Please note that the Field of Use is limited to the use of Chitosan with IL-12 only and does not include the use of the Chitosan with any other antigen. Additionally, the Field of Use may be limited to certain cancer indications.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before December 26, 2013 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and

comments relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 435-4013; Email: [chatterjeesa@od.nih.gov](mailto:chatterjeesa@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** The technology describes the use of chitosan depots with appropriate antigens and/or cytokines for generating an immune response in a subject. Such depots are made by mixing one or more antigens and/or cytokines with chitosan or a chitosan derivative. Similar compositions are described wherein chitosan or a derivative forms a micro- or nanoparticle, which have resulted in a more immunogenic presentation of antigen compared to antigen in solution. Using a representative antigen, the inventors showed that mice vaccinated with the subject depots had increased humoral and cellular immune responses compared to mice vaccinated with antigen alone. Furthermore, comparative mouse studies showed the antigen-specific immune response generated with chitosan depots of this invention to be equipotent to incomplete Freund's adjuvant (IFA) and superior to aluminum hydroxide, a widely used adjuvant for licensed and routinely administered vaccines. Thus, this technology improves upon commonly used adjuvant technology and is widely applicable.

This technology is the first to show that subcutaneous administrations of chitosan and an appropriate antigen, with no other component, can be used for enhancing immune responses. In additional studies, the inventors showed that chitosan is able to maintain a depot of recombinant cytokine. A single subcutaneous injection of chitosan-cytokine outperforms daily injections of recombinant cytokine in both the expansion of draining lymph nodes and in the antigen presenting ability of lymph node cells. This technology is the first to show that chitosan can maintain a depot of cytokine which results in a significant enhancement of the functional effects of a cytokine. This technology can be used for vaccines and immunotherapies against various infectious agents and cancer.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of

this published notice, 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 404.7.

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 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: November 18, 2013.

**Richard U. Rodriguez,**

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

[FR Doc. 2013-28119 Filed 11-22-13; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel.

*Date:* December 2, 2013.

*Time:* 1:30 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Peter Zelazowski, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6902, [peter.zelazowski@nih.gov](mailto:peter.zelazowski@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing

limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; MicroRNAs and Trophoblasts.

*Date:* December 2, 2013.

*Time:* 4:00 p.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Sherry L. Dupere, Ph.D., Chief, Scientific Review Branch, Scientific Review Branch, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-451-3415, [duperes@mail.nih.gov](mailto:duperes@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Assessing Placental Development and Function SBIR.

*Date:* December 3, 2013.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* David Weinberg, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892-7510, 301-435-6973, [David.Weinberg@nih.gov](mailto:David.Weinberg@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Pediatric Orthotics SBIR.

*Date:* December 4, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* David Weinberg, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892-7510, 301-435-6973, [David.Weinberg@nih.gov](mailto:David.Weinberg@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel.

*Date:* December 4, 2013.

*Time:* 10:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.