DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: The Clinical Trials Reporting Program (CTRP) Database (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, 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 February 1, 2013 (Volume 78, Page 7437) 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 Cancer Institute (NCI), 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: 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, contact Jose Galvez, Office of the Director, National Cancer Institute, 2115 East Jefferson Street, Rockville, MD 20852 or call non-toll-free number 301–443–6141 or Email your request, including your address to: jose.galvez@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The Clinical Trials Reporting Program (CTRP) Database, 0925–0600, Expiration Date 3/31/2013—REINSTATEMENT WITH CHANGE, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP Web site to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 33,000.

ESTIMATED ANNUALIZED BURDEN HOURS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meetings

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 meetings.

The meetings 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 Center for Advancing Translational Sciences Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

Date: April 30, 2013.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mohan Viswanathan, Ph.D., Acting Director, Office of Grants Management & Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1084, Bethesda, MD 20892–4874, 301–435–0829, mv10@nih.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of An Exclusive Evaluation Option License: Pre-clinical Evaluation of Anti-tyrosine Kinase-like Orphan Receptor 1 Immunotoxins for the Treatment of Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.


The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to pre-clinical evaluation of lead therapeutic candidates for the development and use of anti-tyro sine kinase-like orphan receptor 1 (ROR1) targeted immunotoxins for the treatment of human ROR1 expressing cancers, wherein the immunotoxin comprises an anti-ROR1 antibody designated as 2A2 and Pseudomonas exotoxin A (PE). Upon expiration or termination of the exclusive evaluation option license, SPEED will have the right to execute an exclusive patent commercialization license which will supersede and replace the exclusive evaluation option license with no broader territory than granted in the exclusive evaluation option license and the field of use will be commensurate with the commercial development plan at the time of conversion.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 24, 2013 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Jennifer Wong, M.S., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4633; Facsimile: (301) 402–0220; Email: wongje@od.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns anti-ROR1 immunotoxin comprising an anti-ROR1 antibody designated as 2A2 and PE as a treatment for human ROR1 expressing cancers. The immunotoxin will comprise a chimeric mouse anti-human receptor tyrosine kinase-like orphan receptor 1 monoclonal antibody whereas the immunotoxin will have a toxin domain derived from PE. PE toxin’s domain have been modified in...