Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 13, 2013. Oral presentations from the public will be scheduled between approximately 12 p.m. and 1 p.m. on May 21, 2013, and between approximately 10:45 a.m. and 11:45 a.m. on May 22, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 3, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 6, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams (*Annmarie.williams@fda.hhs.gov*, 301–796–5966) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 4, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–08218 Filed 4–8–13; 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: 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 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, 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

Type of respondents	Instrument	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Clinical Trials	Initial Registration	5,500	1	1	5,500
	Amendment	5,500	4	1	22,000
	Accrual Updates	5,500	4	15/60	5,500

Dated: April 3, 2013.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, NCI, NIH.

[FR Doc. 2013–08270 Filed 4–8–13; 8:45 am]

BILLING CODE 4140–01–P

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, *mv10f@nih.gov.*

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

Date: May 1, 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, *mv10f@nih.gov.*

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

Date: May 3, 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, *mv10f@nih.gov.*

Dated: April 2, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–08149 Filed 4–8–13; 8:45 am]

BILLING CODE 4140–01–P

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.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent Application 61/172,099 entitled ''Anti-human ROR1 Antibodies'' [HHS Ref. E–097–2009/0–US–01], U.S. Patent Application 60/703,798 entitled ''Mutated *Pseudomonas* Exotoxins with Reduced Antigenicity'' [HHS Ref. E–262–2005/0–US–01], U.S. Patent Application 60/969,929 entitled ''Deletions in Domain II of *Pseudomonas* Exotoxin A that Remove Immunogenic Epitopes with Affecting Cytotoxic Activity'' [HHS Ref. E–292–2007/0–US–01], U.S. Patent Application 61/241,620 entitled ''Improved *Pseudomonas* Exotoxin A with Reduced Immunogenicity'' [HHS Ref. E–269–2009/0–US–01], U.S. Patent Application 61/483,531 entitled ''Recombinant Immunotoxin Targeting Mesothelin'' [HHS Ref. E–117–2011/0–US–01], U.S. Patent Application 61/495,085 entitled ''*Pseudomonas* Exotoxin A with Less Immunogenic T-Cell/or B-Cell Epitopes'' [HHS Ref. E–174–2011/0–US–01], U.S. Patent Application 61/535,668 entitled ''*Pseudomonas* Exotoxin A with Less Immunogenic B-Cell Epitopes'' [HHS Ref. E–263–2011/0–US–01], and all related continuing and foreign patents/patent applications for the technology family, to SPEED BioSystems, LLC. The patent rights in these inventions have been assigned to the Government of the United States of America.

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-tyrosine 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