ESTIMATES OF ANNUAL BURDEN HOURS—Continued

Form name	Type of respondents	Number of respondents	Frequency of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Ped Expedited Study Closure	Board Members	20	1	20/60	7
Adult Expedited Study Chair Response to Required Mod.	Board Members	350	1	15/60	88
Ped Expedited Study Chair Response to Required Mod.	Board Members	150	1	15/60	38
Reviewer Worksheet of Translated Documents	Board Members	15	1	15/60	4
Reviewer Advertisement Checklist	Board Members	10	1	20/60	3

Dated: November 7, 2013.

Vivian Horovitch-Kelley,

Program Analyst, National Institutes of Health.

[FR Doc. 2013–27556 Filed 11–18–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: Cancer Trials Support Unit (CTSU) (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 for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 30, 2013, Vol. 78, p. 53763 and allowed 60-days for public comment. There have been no public comments. 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 or request more information on the proposed project contact: Michael Montello, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number 240–276–6080 or Email your request, including your address to: *montellom@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Cancer Trials Support Unit (CTSU) (NCI), 0925–0624, Expiration Date 12/31/2013, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Cancer Therapy Evaluation Program (CTEP) establishes and supports programs to facilitate the participation of qualified investigators on CTEP-supported studies, and to institute programs that minimize redundancy among grant and contract holders, thereby reducing overall cost of maintaining a robust treatment trials program. Currently guided by the efforts of the Clinical Trials Working Group (CTWG) and the Institute of Medicine (IOM) recommendations to revitalize the Cooperative Group program, CTEP has funded the Cancer Trials Support Unit (CTSU). The CTSU collects standardized forms to process site regulatory information, changes to membership, patient enrollment data, and routing information for case report forms. In addition, CTSU collects annual surveys of customer satisfaction for clinical site staff using the CTSU Help Desk, the CTSU Web site, and the Protocol and Information Office (PIO). An ongoing user satisfaction survey is in place for the Oncology Patient Enrollment Network (OPEN). User satisfaction surveys are compiled as part of the project quality assurance activities and are used to direct improvements to processes and technology. Additionally, there are three surveys that collect information about health professional's interests in clinical trial, potential issues with opening and accruing to a clinical trial and reasons for low accrual.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 25,205.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
CTSU IRB/Regulatory Approval Transmittal Form	Health Care Practitioner	9,000	12	2/60	3,600
CTSU IRB Certification Form	Health Care Practitioner	8,500	12	10/60	17,000
CTSU Acknowledgement	Health Care Practitioner	500	12	5/60	500
Withdrawal from Protocol Participation Form	Health Care Practitioner	50	12	5/60	50
Site Addition	Health Care Practitioner	25	12	5/60	25
CTSU Roster Update Form	Health Care Practitioner	50	12	4/60	40
CTSU Radiation Therapy Facilities Inventory Form.	Health Care Practitioner	20	12	30/60	120

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
CTSU IBCSG Drug Accountability Form	Health Care Practitioner	11	12	10/60	22
CTSU IBCSG Transfer of Investigational Agent Form.	Health Care Practitioner	3	12	20/60	12
Site Initiated Data Update Form	Health Care Practitioner	10	12	10/60	20
Data Clarification Form	Health Care Practitioner	341	12	20/60	1,364
RTOG 0834 CTSU Data Transmittal Form	Health Care Practitioner	60	12	10/60	120
MC0845(8233) CTSU Data Transmittal	Health Care Practitioner	50	12	10/60	100
CTSU Generic Data Transmittal Form	Health Care Practitioner	500	12	10/60	1,000
CTSU Patient Enrollment Transmittal Form	Health Care Practitioner	200	12	10/60	400
CTSU P2C Enrollment Transmittal Form	Health Care Practitioner	15	12	10/60	30
CTSU Transfer Form	Health Care Practitioner	20	12	10/60	40
CTSU System Account Request Form	Health Care Practitioner	20	12	20/60	80
CTSU Request for Clinical Brochure	Health Care Practitioner	75	12	10/60	150
CTSU Supply Request Form	Health Care Practitioner	75	12	10/60	150
CTSU Web Site Customer Satisfaction Survey	Health Care Practitioner	275	1	15/60	69
CTSU Helpdesk Customer Satisfaction Survey	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey	Health Care Practitioner	60	1	15/60	15
PIO Customer Satisfaction Survey	Health Care Practitioner	100	1	5/60	8
Concept Clinical Trial Survey	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey	Health Care Practitioner	1,000	1	5/60	83
Low Accrual Clinical Trial Survey	Health Care Practitioner	1,000	1	5/60	83

Dated: November 7, 2013.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2013–27554 Filed 11–18–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Modified T-cells for the Treatment of Multiple Myeloma

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 to Thirsty Brook Bioscience, Inc., of an exclusive evaluation option license to practice the inventions embodied in the following US Patent Applications (and all continuing applications and foreign counterparts): Serial No. 61/622,6008 entitled, ''Chimeric Antigen Receptors Targeting B-cell Maturation Antigen'' [HHS Ref. E–040–2012/0–US–01]. 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:

''The research, development, and manufacture of chimeric antigen receptor (CAR)-expressing human T-cells directed against B-cell Maturation Antigen (BCMA) for the treatment of multiple myeloma.''

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

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before December 4, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, 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) 435–5560; Facsimile: (301) 402–0220; Email: *mccuepat@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The invention concerns a series of CARs that specifically target BCMA (a.k.a. CD269), a protein that is highly expressed on the surface of multiple myeloma cells. The patent rights include claims to vectors incorporating the CARs, as well as methods of destroying multiple myeloma cells using T-cells engineered to express a CAR.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization 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 evaluation 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: November 13, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–27601 Filed 11–18–13; 8:45 am]

BILLING CODE 4140–01–P