schedule prior to the start of construction. Section 52b.10(g) requires a grantee to provide daily construction logs and monthly status reports upon request at the job site. Section 52b.11(b) requires applicants for a project involving the acquisition of existing facilities to provide the estimated cost of the project, cost of the acquisition of existing facilities, and cost of remodeling, renovating, or altering facilities to serve the purposes for which they are acquired. In terms of recordkeeping requirements: Section 52b.10(g) requires grantees to maintain daily construction logs and monthly status reports at the job site. *Frequency of Response:* On occasion. *Affected Public:* Non-profit organizations and Federal agencies. *Type of respondents:* Grantees. The estimated respondent burden is as follows:

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Reporting:				
Section 52b.9(b)	1	1	.50	.50
Section 2b.10(f)	60	1	1.0	60
Section 2b.10(g)	60	12	1.0	720
Section 2b.11(b)	100	1	1.0	100
Recordkeeping.				
Section 2b.10(g)	60	260	1.0	15,600
Totals	281			16,480.5

The annualized cost to the public, based on an average of 60 active grants in the construction phase, is estimated at: $576,818. There are no Capital Costs to report. There are no operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information and recordkeeping are necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency=s estimate of the burden of the proposed collection of information and recordkeeping, including the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected and the recordkeeping information to be maintained; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection and recordkeeping techniques of other forms of information technology.

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 Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to (202) 395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Jerry Moore, NIH Regulations Officer, Office of Management Assessment, Division of Management Support, National Institutes of Health, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville Maryland 20852; call (301) 496–4607 (this is not a toll free number) or email your request to *jm40z@nih.gov.*

Comments 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.

Dated: October 20, 2011.

Jerry Moore,

NIH Regulations Officer, National Institutes of Health.

[FR Doc. 2011–27850 Filed 10–26–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: New Proposed Collection, Neuropsychosocial Measures Formative Research Methodology Studies for the National Children's Study

Summary: Under the provisions of Section (3507(a)(1)(D)) of the Paperwork Reduction Act of 1995, the National Institutes of Health 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 May 2, 2011, pages 24497–24498, and allowed 60 days for public comment. Two written comments and two verbal comments were received. The verbal comments expressed support for the broad scope of the study. The written comments were identical and questioned the cost and utility of the study. The purpose of this notice is to allow an additional 30 days for public comment. The 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.

Proposed Collection: Title: Neuro-developmental and Psycho-Social Measures Formative Research Studies for the National Children's Study (NCS). *Type of Information Request:* New. *Need and Use of Information Collection:* The Children's Health Act of 2000 (Pub. L. 106–310) states:

(a) *Purpose.*—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) *In General.*—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) Plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

(c) *Requirement.*—The study under subsection (b) shall—

(1) Incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the results of formative research will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of tools to assess language, behavior, and neurodevelopment, psychosocial stress, and health literacy and thereby inform data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain OMB's generic clearance to conduct formative research featuring neuro-developmental and psycho-social measures.

The results from these formative research projects will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard and Main Study neuro-developmental and psycho-social measures in a manner that minimizes public information collection burden compared to burden anticipated if these projects were incorporated directly into either the NCS Vanguard or Main Study. Frequency of Response: Annual [As needed on an on-going and concurrent basis]. Affected Public: Members of the public, researchers, practitioners, and other health professionals. *Type of Respondents:* Women of child-bearing age, infants, children, fathers, community leaders, members, and organizations, health care facilities and professionals, public health, environmental, social and cognitive science professional organizations and practitioners, hospital administrators, cultural and faith-based centers, and schools and child care organizations. These include both persons enrolled in the NCS Vanguard Study and their peers who are not participating in the NCS Vanguard Study. *Annual reporting burden:* See Table 1. The annualized cost to respondents is estimated at: $540,000 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY, NEUROPSYCHOSOCIAL MEASURES

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adult Psychosocial Stress	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants).	4,000	1	1	4,000
Child Developmental Measures	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants).	4,000	1	1	4,000
Health Disparities	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants).	4,000	1	1	4,000
Small, focused survey and instrument design and administration.	NCS participants	4,000	2	1	8,000
	Members of NCS target population (not NCS participants).	4,000	2	1	8,000
	Health and Social Service Providers	2,000	1	1	2,000
	Community Stakeholders	2,000	1	1	2,000
Focus groups	NCS participants	2,000	1	1	2,000
	Members of NCS target population (not NCS participants).	2,000	1	1	2,000
	Health and Social Service Providers	2,000	1	1	2,000
	Community Stakeholders	2,000	1	1	2,000
Cognitive interviews	NCS participants	500	1	2	1,000
	Members of NCS target population (not NCS participants).	500	1	2	1,000
Total		45,000			54,000

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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 Information and Regulatory Affairs, *Attn:* NIH Desk Officer, by e-mail to

OIRA_submission@omb.eop.gov, or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Jamelle E. Banks, Public Health Analyst, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland, 20892, or call a non-toll free number (301) 496–1877 or E-mail your request, including your address to *banksj@mail.nih.gov.*

Comments 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.

Dated: October 20, 2011.

Jamelle E. Banks,

Public Health Analyst, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development, National Institutes of Health.

[FR Doc. 2011–27843 Filed 10–26–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

New Non-HLA–A2 Restricted Human T Cell Receptors (TCRs) That Could Be Used To Treat a Broader Cancer Patient Population Via TCR Adoptive Immunity

Description of Technology: NIH scientists have developed T cell receptors (TCRs) that recognize melanoma antigen family A3 (MAGE–A3) or MAGE–A12 peptide antigens. The TCRs recognize these antigens in the context of major histocompatibility complex (MHC) class I molecules, HLA–A1 and HLA–Cw7, respectively. Since these TCRs are not HLA–A2 restricted, their therapeutic use would expand the number of treatable cancer patients using MAGE–A3 or A12-specific TCR adoptive immunotherapy.

There are twelve MAGE–A superfamily antigens designated A1—A12. Their normal function is not well defined, but in cancer cells they block the functions of tumor suppressor proteins to mediate tumor growth and spreading. The MAGE–A proteins are some of the most widely expressed cancer testis antigens expressed on human tumors. Other than non-MHC expressing germ cells of the testis, normal cells do not express these antigens, which make them ideal targets for cancer immunotherapies anticipated to generate less toxic side effects than conventional cancer treatments. These TCRs deliver a robust immune response against MAGE–A3 or A12 expressing cells and could prove to be a powerful approach for selectively attacking tumors without generating toxicity against healthy cells.

Potential Commercial Applications:

- Personalized immunotherapy for a variety of cancers using human T cells expressing these TCRs
- Component of a combination immunotherapy regimen aimed at targeting specific tumor-associated antigens, including MAGE–A3 and MAGE–A12, expressed by cancer cells.
- A research tool to investigate signaling pathways in MAGE–A3 or MAGE–A12 antigen expressing cancer cells.
- An *in vitro* diagnostic tool to screen for cells expressing MAGE–A3 or MAGE–A12 antigens.

Competitive Advantages:

- Highly expressed targets: MAGE–A proteins (especially MAGE–A3) are some of the most highly expressed cancer testis antigens on human tumors
- Limited side effects: MAGE–A proteins are only expressed on tumor cells and non-MHC expressing testis germ cells. Infused cells expressing these TCRs should target MAGE–A3 or A12 expressing tumor cells with little or no toxicity to the patient's normal cells.
- Not HLA–A2 restricted: Expands patient population treatable with MAGE–A TCRs since they recognize antigen in the context of HLA–A1 or HLA–Cw7.

Development Stage:

- Pre-clinical
- *In vitro* data available

Inventors: Steven A. Rosenberg, Paul F. Robbins, Richard A. Morgan, Steven A. Feldman, and Shiqui Zhu (NCI).

Publication: Chinnasamy N, *et al.* A TCR targeting the HLA–A*0201-restricted epitope of MAGE–A3 recognizes multiple epitopes of the MAGE–A antigen superfamily in several types of cancer. J Immunol. 2011 Jan 15;186(2):685–696. [PMID 21149604].

Intellectual Property: HHS Reference No. E–266–2011/0—U.S. Patent Application No. 61/535,086 filed 15 September 2011.

Related Technology: HHS Reference No. E–236–2010/0—U.S.Patent Application No. 61/405,668 filed 22 October 2010.

Licensing Contact: Samuel E. Bish, Ph.D.; (301) 435–5282; *bishse@mail.nih.gov.*

Collaborative Research Opportunity: The Surgery Branch of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize T cell receptors that target cancer/testis antigens for use in cancer adoptive immunotherapy. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Antiandrogen Small Molecules for the Treatment of Prostate Cancer

Description of Technology: The present licensing opportunity is for a new class of small molecule compounds, and the method of using them to treat prostate cancer. This year it is estimated there will be over 32,000 deaths from prostate cancer showing an unmet need for a more effective treatment particularly for castrate-resistant prostate cancer (CRPC). CRPC is characterized by androgen-independent cancer cells that have adapted to the depletion of hormones and continue to grow. Abnormal androgen receptor signaling is known to drive advanced castrate-resistant prostate cancer. The small molecule compounds of the instant invention are antiandrogens that target androgen receptor signaling in both androgen-independent and androgen-sensitive androgen receptor activity, and androgen receptors that are resistant to the current antiandrogens available. Unlike the currently available