information. FDA received one comment which was related to the Paperwork Reduction Act burden associated with this collection of information.

The comment indicated that table 2 in the 60-day notice was not clear if it represented burden for all respondents, or just one respondent. In addition, the commenter noted that if table 2 represented the estimated burden for all respondents, that they did not agree with the accuracy of FDA's estimate, as the table appears to assume that each respondent creates one SOP per each 21 CFR section listed. The commenter felt that this assumption is not correct for large companies, who could possibly have several thousand systems, each requiring their own SOPs. If this were the case, the recordkeeping burden in Table 2 would be severely understated.

FDA's response is to note that the recordkeeping burden in table 2 is an estimate of both large and small firms, and the burden represented in the table is an average of the burden for all forms. In addition, the recordkeeping requirements ask each respondent to this collection maintain a set of SOPs which could help the company and FDA in the future determine the methodology the company employed in its systems to ensure that the electronic signatures for its employees on documents submitted to the FDA were valid, if needed. Over the years, FDA developed this recordkeeping burden by listening to feedback from its staff and external stakeholders, and feels that the burden adequately represents the average burden a firm might expend to complete the recordkeeping requirements for this collection.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The Agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records. The respondents will be businesses and other for-profit organizations, State or local governments, Federal Agencies, and nonprofit institutions.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
11,100	4,500	1	4,500	1	4,500
Total					4,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
11.10	2,500	1	2,500	20	50,000
11.30	2,500	1	2,500	20	50,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					280,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 5, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17155 Filed 7–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request; Study Logistic Formative Research Methodology Studies for the National Children's Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NIHCD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval. This proposed information collection was previously published in the **Federal Register** on April 27, 2011, pages 23605–23606, and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection

Title: Study Logistics Formative Research Methodology Studies for the National Children's Study (NCS).

Type of Information Collection Request: Generic Clearance.

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 new and existing study measures, participant communication techniques, and technologies being utilized, 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 relating to instrument design and modality with a view to reduce item and unit non-response to Study instruments while preserving scientific quality.

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 instrument design and modality 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, fathers, health care facilities and professionals, public health professional organizations and practitioners, 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: $300,000 (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, STUDY OPERATIONS

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
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		21,000			30,000

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 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Sarah L. Glavin, Deputy Director, 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 non-toll free number (301) 496–1877 or E-mail your request, including your address to *glavins@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: June 21, 2011.

Sarah L. Glavin,

Deputy Director, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

[FR Doc. 2011–17201 Filed 7–7–11; 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.

Breakthrough Immunotherapy for Brain Cancer: Epidermal Growth Factor Receptor Variant III Chimeric Antigen Receptors

Description of Technology: Scientists at the National Institutes of Health (NIH) have developed chimeric antigen receptors (CARs) with high affinity for the epidermal growth factor receptor variant III (EGFRvIII) to use as a promising immunotherapy for aggressive brain cancer (glioblastoma) as well as several other malignancies. CARs are hybrid proteins consisting of the portion of an antibody that recognizes a cancer antigen, in this case human monoclonal antibody 139 which recognizes EGFRvIII, fused to protein signaling domains that serve to activate the CAR-expressing cell. Human cells that express CARs, most notably T cells, can recognize specific tumor antigens in an MHC-unrestricted manner with high reactivity and mediate an immune response that promotes robust tumor cell elimination.

Advantages

• EGFRvIII CAR immunotherapy is a breakthrough treatment for glioblastomas, a cancer with no other effective treatment option.

• EGFRvIII CARs can cross the blood-brain barrier, are expected to target only tumor cells, and thus, generate fewer side effects than other brain cancer treatment approaches.

• With the advent of Provenge®, personalized immunotherapy is becoming more widely accepted as a viable cancer treatment option.

Applications

• Immunotherapeutics to treat and/or prevent the recurrence of a variety of cancers that overexpress human EGFRvIII, primarily glioblastoma multiforme (GBM). About half of GBM tumor cells express the EGFRvIII antigen. Other cancers that overexpress EGFRvIII include breast, ovarian, prostate, bladder, colorectal, non-small cell lung carcinomas, and head and neck squamous cell carcinomas.

• A personalized cancer treatment strategy for patients whose tumor cells express EGFRvIII whereby the patient's own T cells are isolated, engineered to express the EGFRvIII specific CAR, and re-infused into the patient to attack the tumor.

EGFRvIII is a rare antigen in that is highly expressed by tumor cells, but not expressed by other cells in the body. This cancer antigen is expressed on nearly 50% of GBM tumor cells and also in other tumor types, such as other nervous system cancers and head and neck cancers. There exist very few, if any, effective treatments for GBM, so the expected clinical benefit of an anti-EGFRvIII CAR to patients is expected to be a therapeutic breakthrough for treatment of this cancer. These CARs are expected to combine high affinity recognition of EGFRvIII provided by the antibody portion with the target cell killing activity of cytotoxic T cells. Infusion of these EGFRvIII-specific CARs into patients could prove to be a powerful new immunotherapeutic tool for treating brain cancers, a type of cancer with a long-felt need for breakthrough therapeutics.

Development Status: This technology could soon be ready for clinical development. A clinical protocol to utilize an EGFRvIII CAR to treat GBM is currently under review at NIH.

Inventors: Richard A. Morgan and Steven A. Rosenberg (NCI).

Patent Status: U.S. Provisional Application No. 61/473,409 filed April 8, 2011 (HHS Reference No. E–148–2011/0–US–01).

Related Technologies

• E–269–2010/0—U.S. Provisional Application No. 61/384,931 filed September 21, 2010.

• E–236–2010/0—U.S. Provisional Application No. 61/405,931 filed October 22, 2010.

• E–205–2009/0—PCT Application No. PCT/US2010/048701 filed September 14, 2010, which published as WO2011/041093 on April 7, 2011.

Relevant Publications

1. Weber R, *et al.* U.S. Patent No. 7,628,986 issued December 8, 2009 entitled ''Antibodies Directed to the Deletion Mutants of Epidermal Growth Factor Receptor and Uses Thereof''.

2. Carter B.S., *et al.* U.S. Patent Application No. 12/444,090 filed April 2, 2009 entitled ''Chimeric T–Cell Receptors and T–Cells Targeting EGFRvIII on Tumors''.

3. Bullian SS, *et al.* Genetically engineered T cells to target EGFRvIII expressing glioblastoma. *J Neurooncol.* 2009 Sept;94(3):373–382. [PMID: 19387557].

4. Ohno M, *et al.* Retrovirally engineered T-cell based immunotherapy targeting type III variant epidermal growth factor receptor, a glioma-associated antigen. *Cancer Sci.* 2010 Dec;101(12):2518–2524. [PMID: 20880333].

Licensing Status: Available for licensing.

Licensing Contact: Samuel E. Bish, PhD; 301–435–5282; *bishse@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize cell-based immunotherapies targeting EGFRvIII expressing cancers. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

An Improved Anti-Mesothelin Immunotoxin for Treatment of Mesothelioma, Lung Cancer, Ovarian Cancer and Pancreatic Cancer

Description of Technology: Mesothelin is a cell surface glycoprotein that is highly expressed in many cancers (*e.g.,* malignant mesothelioma, lung cancer, ovarian cancer, and pancreatic cancer). Because of its differential expression, mesothelin is an excellent