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

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response (in hours)</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.10</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>11.30</td>
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<td>11.300</td>
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<td></td>
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</tr>
</tbody>
</table>

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

### TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping (in hours)</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.10</td>
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<td>11.30</td>
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<td>11.300</td>
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<td></td>
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</tr>
</tbody>
</table>

†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]
(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>
<thead>
<tr>
<th>Data collection activity</th>
<th>Type of respondent</th>
<th>Estimated number of respondents</th>
<th>Estimated number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Estimated total annual burden hours requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small, focused survey and instrument design and administration.</td>
<td>NCS participants ..........................</td>
<td>4,000</td>
<td>2</td>
<td>1</td>
<td>8,000</td>
</tr>
<tr>
<td></td>
<td>Members of NCS target population (not NCS participants).</td>
<td>4,000</td>
<td>2</td>
<td>1</td>
<td>8,000</td>
</tr>
<tr>
<td></td>
<td>Health and Social Service Providers.</td>
<td>2,000</td>
<td>1</td>
<td>1</td>
<td>2,000</td>
</tr>
<tr>
<td></td>
<td>Community Stakeholders ....</td>
<td>2,000</td>
<td>1</td>
<td>1</td>
<td>2,000</td>
</tr>
<tr>
<td></td>
<td>NCS participants ..........................</td>
<td>2,000</td>
<td>1</td>
<td>1</td>
<td>2,000</td>
</tr>
<tr>
<td></td>
<td>Members of NCS target population (not NCS participants).</td>
<td>2,000</td>
<td>1</td>
<td>1</td>
<td>2,000</td>
</tr>
<tr>
<td></td>
<td>Health and Social Service Providers.</td>
<td>2,000</td>
<td>1</td>
<td>1</td>
<td>2,000</td>
</tr>
<tr>
<td></td>
<td>Community Stakeholders ....</td>
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<tr>
<td></td>
<td>NCS participants ..........................</td>
<td>500</td>
<td>1</td>
<td>2</td>
<td>1,000</td>
</tr>
<tr>
<td></td>
<td>Members of NCS target population (not NCS participants).</td>
<td>500</td>
<td>1</td>
<td>2</td>
<td>1,000</td>
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<tr>
<td>Total ...............................</td>
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<td>21,000</td>
<td>...............................................</td>
<td>...............................................</td>
<td>30,000</td>
</tr>
</tbody>
</table>

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.
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: 301–435–3121 or fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Licensing Contact: hewesj@mail.nih.gov


Licensing Status: Available for licensing.

Dated: June 21, 2011.
Sarah L. Glavin,
Deputy Director, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

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

Related Technologies


Relevant Publications


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...