These regulatory changes are expected to influence tobacco-product risk perceptions, exposures, and use patterns in the short term, and to reduce tobacco-related morbidity and mortality in the long term. By measuring and accurately reporting tobacco product use behaviors and health effects associated with these regulatory changes, this study will provide an empirical evidence base to inform the development, implementation, and evaluation of tobacco-product regulations in the U.S.

Frequency of Response: Annually.

Affected Public: Individuals or households. Type of Respondents: Youth (ages 12–17) and Adults (ages 18+). The annual reporting burden for the field test is presented in Table 1, and the annual reporting burden for the baseline data collection is presented in Table 2. The annualized cost to respondents for the field test is estimated at: $24,495; and the annualized cost to respondents for the baseline data collection is: $1,947,567. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

### TABLE 1—PATH STUDY FIELD TEST HOUR BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Type of respondents</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>Adults—Household Screener</td>
<td>1,295</td>
<td>1</td>
<td>22/60</td>
<td>479</td>
</tr>
<tr>
<td>Adults—Individual Screener</td>
<td>840</td>
<td>1</td>
<td>6/60</td>
<td>84</td>
</tr>
<tr>
<td>Adults—Extended Interview</td>
<td>590</td>
<td>1</td>
<td>1 26/60</td>
<td>844</td>
</tr>
<tr>
<td>Adults—Tobacco Use Form</td>
<td>590</td>
<td>1</td>
<td>2/60</td>
<td>18</td>
</tr>
<tr>
<td>Youth—Extended Interview</td>
<td>100</td>
<td>1</td>
<td>55/60</td>
<td>92</td>
</tr>
<tr>
<td>Adult—Parent Interview</td>
<td>100</td>
<td>1</td>
<td>24/60</td>
<td>40</td>
</tr>
<tr>
<td>Total</td>
<td>3,515</td>
<td>1</td>
<td></td>
<td>1,557</td>
</tr>
</tbody>
</table>

### TABLE 2—PATH STUDY BASELINE HOUR BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Type of respondents</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>Adults—Household Screener</td>
<td>100,983</td>
<td>1</td>
<td>22/60</td>
<td>37,364</td>
</tr>
<tr>
<td>Adults—Individual Screener</td>
<td>63,000</td>
<td>1</td>
<td>6/60</td>
<td>6,300</td>
</tr>
<tr>
<td>Adults—Extended Interview</td>
<td>42,730</td>
<td>1</td>
<td>1 26/60</td>
<td>61,104</td>
</tr>
<tr>
<td>Adults—Tobacco Use Form</td>
<td>42,730</td>
<td>1</td>
<td>2/60</td>
<td>1,282</td>
</tr>
<tr>
<td>Youth—Extended Interview</td>
<td>16,857</td>
<td>1</td>
<td>55/60</td>
<td>15,508</td>
</tr>
<tr>
<td>Adult—Parent Interview</td>
<td>16,857</td>
<td>1</td>
<td>24/60</td>
<td>6,743</td>
</tr>
<tr>
<td>Total</td>
<td>283,157</td>
<td>1</td>
<td></td>
<td>128,301</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 enhance the quality, utility, and clarity of the information to be 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.

**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 Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Blvd., Room 5185; 301–443–8755; email PATHprojectofficer@mail.nih.gov.

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.


Helio Chaves,
Deputy Executive Officer (OM Director),
NIDA.

[PR Doc. 2012–12017 Filed 5–17–12; 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.

**FOR FURTHER INFORMATION CONTACT:** 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.

**Java Applet for Modeling Human Metabolism and Energy Expenditure for Adaptive Dieting and Exercise Regimens**

**Description of Technology:** Known methods for predicting weight loss fail to account for slowing of metabolism as weight is lost and therefore overestimate the degree of weight loss. While this limitation of the 3500 Calorie per pound rule has been known for some time, it was not clear how to dynamically account for the metabolic slowing. The invention provides a Java applet for modeling of human metabolism to improve the weight change predictions. The model has been validated using previously published human data and the model equations have been published. A web-based implementation of the published dynamic model has been created to allow users to perform simulations for planning weight loss interventions in adults and accounts for individual differences in metabolism and body composition.

**Potential Commercial Applications**

- Obesity.
- Weight Loss.

**Competitive Advantages:** Personalized predictions.

**Development Stage:** Prototype.

**Inventors:** Kevin Hall, Carson Chou, Drhuvu Chandramohan (all of NIDDK).


**Licensing Contact:** Patrick McCue, Ph.D.; 301–435–5560; mccuepat@mail.nih.gov.

**Collaborative Research Opportunity:** The NCI Center for Cancer Research, Laboratory of Cancer Biology and Genetics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Methods for Selecting Cancer Patients for HDACi/mTORi Combination Therapy. For collaboration opportunities, please contact Beverly Mock et al. (NCI).

**Gli-Similar 3 (GLIS3) Knock Out (KO) Mice as Models to Screen Therapeutics for Diabetes, Polycystic Kidney Disease, and Hypothyroidism**

**Description of Technology:** Gli1–3 proteins constitute a subfamily of the Krüppel-like zinc finger transcription factors that are closely related to the Gli family. Mutations in human GLIS3 have been implicated in a syndrome characterized by neonatal diabetes and congenital hypothyroidism (NDH) and in some patients accompanied by polycystic kidney disease, glaucoma, and liver fibrosis. To further identify and study the physiological functions of GLIS3,
NIEHS investigators generated mice in which GLIS3 is ubiquitously knocked out (GLIS3–KO) or conditionally knocked out in a cell type-specific manner. GLIS3–KO mice develop polycystic kidney disease, hypothyroidism, and neonatal diabetes, as indicated by the development of hyperglycemia and hypoinsulinemia. The pancreatic endocrine cells, particularly insulin-producing pancreatic beta cells, are greatly diminished in these mice. The pancreas-selective knockout mice GLIS3(Pdx1-Cre) develop severe diabetes within 2–3 months, much later than the GLIS3–KO mice. The kidney-selective knockout of GLIS3 (GLIS3(Ksp-Cre)) mice lack expression of GLIS3 in the collecting ducts and develop severe polycystic kidney disease within a period of 2–4 months. These mice can be used as models to screen therapeutics for diabetes, polycystic kidney disease, and hypothyroidism.

**Potential Commercial Applications**
- Therapeutic target in the management of diabetes, polycystic kidney disease, and hypothyroidism.
- Models to test therapeutic drugs for diabetes, polycystic kidney disease, and hypothyroidism.

**Competitive Advantages**
- Provides opportunity to discover upstream signals that regulate GLIS3 activity.
- Can be used in stem cell therapy in diabetes treatment.
- Excellent model to study the role of GLIS3 in neonatal diabetes.

**Development Stage**
- Early-stage.
- Pre-clinical.
- In vivo data available (animal).

Inventors: Anton M Jetten, Hong Soon Kang, Kristin Lichti-Kaiser (all of NIEHS).

**Publications**

**Related Technologies**

**Microarray for Detection and Subtyping of Human Influenza Viruses**

**Description of Technology:** Available for licensing and commercial development are a novel influenza virus microarray and methods for using the microarray for the identification of existing and new types and subtypes of human influenza viruses. There are three types of influenza viruses, type A, B and C. Influenza types A or B viruses cause epidemics of disease almost every winter, with type A causes major pandemic periodically. Influenza type A viruses are further divided into subtypes based on two proteins on the surface of the virus. These proteins are called hemagglutinin (H) and neuraminidase (N). There are 16 known HA subtypes and 9 known NA subtypes of influenza A viruses. Each subtype may have different combination of H and N proteins. Although there are only three known A subtypes of influenza viruses (H1N1, H1N2, and H3N2) currently circulating among humans, many other different strains are circulating among birds and other animals and these viruses do spread to humans occasionally. There is a requirement for sensitive and rapid diagnostic techniques in order to improve both the diagnosis of infections and the quality of surveillance systems. This microarray platform tiles the genomes of all types/subtypes of influenza viruses, and is capable of correctly identifying all 3 types/subtypes of influenza viruses from an influenza vaccine sample.

**Potential Commercial Applications**
- Detection and identification of human influenza viruses.
- Efficient discovery of new subtypes of influenza viruses.
- Diagnosis of influenza outbreaks.

**Development Stage**
- Pre-clinical.
- In vitro data available.

Inventors: Xiaolin Wu, David J. Munroe, Cassio S. Baptista, Elizabeth Shannon (all of NCI).


**Collaborative Research Opportunity:** The NIEHS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize GLIS3 Knock Out Mice. For collaboration opportunities, please contact Elizabeth M. Denholm, Ph.D. at denholmle@niehs.nih.gov.

**M3 Muscarinic Receptor Knockout Mice (Chrm3 tm1Jwe) for the Study of Obesity and Other Metabolic Disorders**

**Description of Mouse:** The five Muscarinic Acetylcholine (ACh) receptors are G-protein coupled receptors (M1R–M5R). M3 muscarinic ACh receptors are present in the central nervous system and the periphery. M3R knockout mice are viable and fertile, and have no major morphological abnormalities. They have a lean phenotype due to a combination of reduced caloric intake and increased energy expenditure. Because of their lean phenotype, M3R knockout mice have improved glucose tolerance and increased insulin sensitivity. Pharmacological blockade of central M3Rs may be a novel strategy for the treatment of obesity and associated metabolic disorders.

In the airway, vagally-mediated bronchoconstriction responses were abolished in M3R knockout mice in vivo, suggesting that M3R antagonists may be useful in the treatment of chronic obstructive pulmonary disease (COPD) and asthma. Studies with M3R knockout mice also have shown that the M3R is the major muscarinic receptor mediating ACh-induced glandular secretion from exocrine and endocrine glands, including the secretion of insulin from pancreatic beta cells.

**Potential Commercial Applications:** Animal model to study COPD and metabolism.

**Competitive Advantages:** M3R knockout mice are viable and fertile, and have no major morphological abnormalities.

**Development Stage:** Pre-clinical.

**Developer of Mouse:** Jürgen Woss, Ph.D. (NIDDK).

**Publication:** Yamada M, et al. Mice lacking the M3 muscarinic acetylcholine receptor are hypophagic and lean. Nature. 2001 Mar 8;410(6825):207–12. [PMID 11242080]
Use of E-Selectin Tolerization as Treatment for Immunological and Vascular-Related Disorders

**Description of Technology:** This technology relates to the mucosal delivery (e.g. intranasal) of an E-selectin fragment as a tolerization agent for the prevention and treatment of immunological and vascular-related disorders, including stroke and multiple sclerosis (MS) as well as rare or orphan diseases involving vascular modulated disorders.

E-selectin is an adhesion molecule that is expressed on endothelial cells lining blood vessels in response to certain localized cytokines, making the endothelial surface pro-coagulant, pro-inflammatory and/or immunoreactive. Such changes on the endothelial surface have been linked to the development of vascular-related disorders like stroke, as well as immune regulated diseases such as MS.

Intranasal administration of E-selectin, using a tolerizing dosing schedule, induces an immunological tolerance to E-selectin. T regulatory cells become targeted to activating blood vessel segments, where they release immunomodulatory cytokines such as IL-10. This release of cytokines suppresses local pro-coagulant, pro-inflammatory and immunoreactive effects. Thus, administration of E-selectin as a tolerizing agent will provide a targeted therapeutic approach, impacting only affected sites in the endothelium.

**Potential Commercial Applications:** Treatment of diseases biologically based on vascular initiated immune regulation. Such disorders include prevention of secondary stroke, MS, Alzheimer’s, Parkinson’s, rheumatoid arthritis, type 1 diabetes, and psoriasis.

**Competitive Advantages**

- Low doses utilized thus minimizing potential side effects.
- Animal data are available, with further studies currently on-going.
- Administration through the intranasal route represents a less invasive mode of delivery.
- FDA pre-IND meetings have been held and FDA communications are ongoing.

**Development Stage**

- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

**Inventors:** John M. Hallenbeck, Maria Spatz, Hidetaka Takeda, Hideaki Wakita (all of NINDS)

**Publications**


**Intellectual Property**


**Use of E-Selectin Tolerization as Treatment for Immunological and Vascular-Related Disorders**


**Licensing Contact:** Jaime M. Greene, M.S.; 301–435–5559; greenejaime@mail.nih.gov

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**Publications**