Based on the number of manufacturers that would be covered by the guidance, we estimate that approximately 5,000 firms will add the following to their COOP: (1) Instructions for reporting adverse events; and (2) a plan for submitting stored reports that were not submitted within regulatory timeframes. We estimate that each firm will take approximately 50 hours to prepare the adverse event reporting plan for its COOP.

We estimate that approximately 500 firms will be unable to fulfill normal adverse event reporting requirements because of conditions caused by an influenza pandemic and that these firms will notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist. Although we do not anticipate such pandemic influenza conditions to occur every year, for purposes of the PRA, we estimate that each of these firms will notify FDA approximately once each year, and that each notification will take approximately 8 hours to prepare and submit.

Concerning the recommendation in the guidance that firms unable to fulfill normal adverse event reporting requirements maintain documentation of the conditions that prevent them from meeting these requirements and also maintain records to identify what adverse event reports have been stored and when the reporting process is restored, we estimate that approximately 500 firms will each need approximately 8 hours to maintain the documentation and that approximately 500 firms will each need approximately 8 hours to maintain the records. Therefore, the total recordkeeping burden that would result from the guidance would be 258,000 hours.

The guidance also refers to previously approved collections of information found in FDA's adverse event reporting requirements in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170, 640.73, 1271.350, and part 803. These regulations contain collections of information that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520) and are approved under OMB control numbers 0910–0116, 0910–0291, 0910–0230, 0910–0308, 0910–0437, and 0910–0543. In addition, the guidance also refers to adverse event reports for nonprescription human drug products marketed without an approved application and dietary supplements required under sections 760 and 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379aa and 379aa–1), which include collections of information approved under OMB control numbers 0910–0636 and 0910–0635.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notify FDA when normal reporting is not feasible	500	1	500	8	4,000

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Add adverse event reporting plan to COOP	5,000	1	5,000	50	250,000
Maintain documentation of influenza pandemic conditions and resultant high absenteeism	500	1	500	8	4,000
Maintain records to identify what reports have been stored and when the reporting process was restored	500	1	500	8	4,000
					258,000

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

Dated: August 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18944 Filed 8–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, 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. 209 and 37 CFR part 404 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Web Application for Managing the Request Process for Order Set Development Within an Electronic Health Record

Description of Technology: Technology to empower clinical staff in requesting and designing order sets can be transformative for hospitals and other health care organizations. This software is proving itself vital in building greater

order set development efficiencies and in communication among key stakeholders responsible for certain aspects of an order set within an organization. By providing end users the necessary tools (e.g., ordering items off of an available ''menu'' of orderable items within an EHR) to build order sets on their own time and under their own accord has been met with critical acclaim. This empowerment to the end user and the deprecation of any manual process has been a primary goal of this software.

With less time spent translating and managing order sets from the conceptual stage to release, organizational staff can now spend more time working through more pressing clinical issues with their customers; and since this software can standardize and manage the process by which order sets are developed, less error-prone and more timely stages of an order set request with clinical and organizational staff become the norm. Most importantly, this software enables all of those end-users targeted communication pathways in which to operate and end users can now gleam a greater picture of the entire order set development needs and direction—bringing concept to release a quicker pathway than what was available for them in the past.

Potential Commercial Applications: Electronic Health Records.

Competitive Advantages

- Web-based Application
- Platform for development of Order Sets
- Customizable for extension to EHR of choice
- Facilitation of workflow process and approval sign-off

Development Stage: Prototype.

Inventors: Christopher Siwy, Josanne Revoir, Jon McKeeby (all of NIHCC).

Intellectual Property: HHS Reference No. E–187–2014/0—Software. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich, Esq., CLP; 301–435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The National Institutes of Health Clinical Center is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Electronic Health Records. For collaboration opportunities, please contact Eric Cole at *colee@cc.nih.gov* or 301–451–4430.

Implantable Medical Devices With Electric Current Retrieval Assist

Description of Technology: Implantable devices, such as filters and stents, typically include structures that anchor to surrounding tissue. To prevent blood clots from reaching the heart, an IVC filter may be implanted into the patient. While generally effective at preventing movement of post-implantation, traditional anchors present challenges when attempting to remove the device from the subject. In particular, the tissue to which the device is anchored may grow around the anchors making removal difficult. The invention pertains to an implantable device (e.g., an IVC filter) with a plurality of expandable members each having a portion that comes into contact with the tissue of a subject when expanded. A force is then provided to the retrieval portion to collapse the implantable device. An electrical current (approx. 0.2 and 0.55 Amps) is also provided to the portions of the expandable members that come into contact with the tissue of the subject via the retrieval apparatus by way of a conductive snare in one or more of the expandable members.

Potential Commercial Applications

- Blood clot prevention
- Stent removal
- Implantation

Competitive Advantages: Ease of removal from subject tissue.

Development Stage

- Early-stage
- In vitro data available
- In vivo data available (animal)

Inventors: Bradford Wood and Hayet Amalou (NIHCC).

Publication: Amalou H, et al. Electrically conductive catheter inhibits bacterial colonization. J Vasc Interv Radiol. 2014 May;25(5):797–802. [PMID 24745908].

Intellectual Property: HHS Reference No. E–088–2014/0—U.S. Provisional Patent Application 61/968,757 filed March 21, 2014.

Related Technologies: HHS Reference No. E–244–2000/1—U.S. Patent Nos. 6,676,657, issued January 13, 2004, and 7,122,033, issued October 17, 2006 (Endoluminal Radiofrequency Cauterization System).

Licensing Contact: Michael Shmilovich, Esq., CLP; 301–435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The National Institutes of Health Clinical Center is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize conduction assisted stent removal. For collaboration opportunities, please contact Ken Rose, Ph.D., JD at *rosek@mail.nih.gov* or 240–276–5509.

Cancer Immunotherapy Using Virus-Like Particle Containing Alphavirus Replicons Coding for Therapeutic Proteins

Description of Technology: One major challenge in development of effective cancer therapies is a lack of universal, cancer specific markers in target cells. Current cancer therapies heavily rely on surgery, chemotherapy, and radiation therapy. Such treatments, although successful in some limited cases, are less effective long term and often result in highly resistant populations of cancer cells that are less susceptible to successive applications of chemotherapy and radiation. Additionally, the systemic application of these therapies and lack of specificity can lead to adverse side effects. Considerable effort has thus been devoted to finding new ways of identifying and specifically targeting extracellular cancer markers using antibody based therapies. However, diminished access to new cancer cell surface markers has limited the development of corresponding antibodies. Investigators at the National Cancer Institute have discovered a novel method employing presentation of intracellular cancer antigens on the cell surface to convert a tumor into induced antigen presenting cells (APCs). The technology utilizes virus-like particle (VLP) mediated RNA delivery of therapeutic proteins, HLA II and CD80, to directly convert cancer cells into APCs to activate helper and cytotoxic T cells against the tumor. This immunotherapy has the potential to induce tumor specific responses with minimal toxicity to neighboring healthy cells.

Potential Commercial Applications

- Cancer immunotherapy
- Cancer vaccine

Competitive Advantages

- Targeted delivery
- Therapy is effective for any cancer antigen, known or unknown
- Simple procedure
- More robust immune response

Development Stage

- In vitro data available
- In vivo data available (animal)
- Prototype

Inventors: Stanislaw J. Kaczmarczyk and Deb K. Chatterjee (NCI/Leidos).

Intellectual Property: HHS Reference No. E–050–2014/0—U.S. Provisional Application No. 61/916,384 filed December 16, 2013.

Related Technology: HHS Reference No. E–264–2011/0—PCT Application No. PCT/US2013/031876 filed March 15, 2013.

Licensing Contact: Vince Contreras, Ph.D.; 301–435–4711; *vince.contreras@nih.gov.*

Collaborative Research Opportunity: The NCI Technology Transfer Center is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Cancer Immunotherapy Using Virus-like Particles. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Novel Anti-HIV Compounds (Peptides or Peptide Mimetics)

Description of Technology: The subject invention describes a new class of compounds (such as peptides or mimetics) that target viral RNAs and inhibit viral life cycle through blocking the viral recognition process. More specifically, these compounds are the first against an RNA Target as currently there is no clinical drug against any RNA targets in treatment of any types of human disease. Moreover, in contrast to all market available anti-HIV drugs that are complicated by the development of resistance and substantial side-effect, these compounds would unlikely develop any side effects because of its very high specificity against only viral RNA. In addition, these compounds may be further linked to a detectable label. Thus, these compounds have the potential to be used as a new class of systemic drug for the treatment of HIV infection and to be developed to diagnostic kit/devices.

Potential Commercial Applications

- HIV therapeutics
- Diagnostic

Competitive Advantages

- No current anti-HIV drug targets against the viral nuclear export activity.
- High binding affinity.
- Permeability of cell membrane because they are positively charged.
- No side effects because of its very high specificity only to viral RNAs.

Development Stage

- Early-stage
- In vitro data available
- Prototype

Inventors: Yun-Xing Wang, Liu Yu, Ping Yu, Ina O'Carroll (all of NCI).

Publication: Fang X, et al. An unusual topological structure of the HIV–1 Rev response element. Cell. 2013 Oct 24;155(3):594–605. [PMID 24243017].

Intellectual Property: HHS Reference No. E–019–2014/0—U.S. Provisional Patent Application No. 61/894,849 filed October 23, 2013.

Licensing Contact: Sally H. Hu, Ph.D., M.B.A.; 301–435–5606; *hus@mail.nih.gov*.

A3 Adenosine Receptor Agonists for Treating Chronic Neuropathic Pain

Description of Technology: Chronic neuropathic pain (NP) is a widespread condition that is often associated with diabetes, cancer, injury as well as a variety of other diseases. Current therapies for NP are not always effective and patients suffer from serious side effects, such as liver toxicity and addiction. Opioids, while effective against acute pain, are not the first line of treatment for chronic NP because of their addictive qualities and low efficacy. Thus, there is an unmet need for chronic neuropathic pain treatment that operates on a different mechanism.

The current invention describes selective A3 Adenosine Receptor agonists and their in vivo activity reducing or preventing development of chronic neuropathic pain in an animal model.

Potential Commercial Applications: New treatment for chronic neuropathic pain associated with diabetes, cancer, injury, etc.

Competitive Advantages: The compounds are consistently highly selective and have smaller molecular weight, thus greater oral bioavailability is possible.

Development Stage

- Early-stage
- In vitro data available
- In vivo data available (animal)

Inventors: Dr. Kenneth A. Jacobson (NIDDK), Dr. Dilip K. Tosh (NIDDK), Daniela Salvemini (Saint Louis University).

Intellectual Property: HHS Reference No. E–742–2013/0—U.S. Provisional Patent Application No. 61/909,742 filed November 27, 2013.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize small molecules for neuropathic pain. For collaboration opportunities, please contact Marguerite J. Miller at *Marguerite.Miller@nih.gov* or 301–496–9003.

AAV-Vectors for Treatment of Glycogen Storage Disorders

Description of Technology: Adeno-Associated Virus Vectors for the treatment of glycogen storage disease, particularly glycogen storage disease type Ia, are disclosed. Glycogen storage disease type Ia (GSD-Ia or von Gierke disease) is caused by a deficiency in glucose-6-phosphatase-α (G6Pase-α or G6PC). Patients affected by GSD-Ia are unable to maintain glucose homeostasis and present with fasting hypoglycemia, growth retardation, hepatomegaly, nephromegaly, hyperlipidemia, hyperuricemia, and lactic academia. There is currently no cure for GSD-Ia deficiency disorder. NIH investigators have constructed a novel gene therapy vector by placing the G6PC gene in a novel virus-based vector, named ssAAV-G6PC-GPE. The expression of G6Pase-α in ssAAV-G6PC-GPE is directed by the human *G6PC* promoter/enhancer at nucleotides -2864 to -1 (GPE) and this vector also contains an intron. The G6pc−/− mice treated with ssAAV-G6PC-GPE vector exhibited normal levels of blood glucose, blood metabolites, hepatic glycogen, and hepatic fat. This vector was compared with a dsAAV-G6Pase vector which differed from the NIH vector that it is double stranded and contained much smaller G6PC promoter. The results showed that the ssAAV-G6PC-GPE vector directed significantly higher expression of G6Pase-alpha and achieved greater reduction in hepatic glycogen storage while better tolerating fasting conditions. The results also showed that the enhancer elements upstream the human *G6PC* minimal promoter contained within the ssAAV-G6PC-GPE vector are responsible for the increased efficacy in treating GSD-Ia mice.

Potential Commercial Applications: Gene therapy for glycogen storage disorders, specifically caused by the deficiency of G6Pase-α.

Competitive Advantages: Comparative studies showed that the ssAAV-G6Pase-GPE vector is more efficacious than other candidate therapy vectors.

Development Stage

- In vitro data available
- In vivo data available (animal)

Inventors: Drs. Janice Y. Chou (NICHD) and Barry J. Byrne (Univ. of Florida).

Publication: Lee YM, et al. The upstream enhancer elements of the G6PC promoter are critical for optimal

G6PC expression in murine glycogen storage disease type Ia. Mol Genet Metab. 2013;110(3):275–80. [PMID 23856420].

Intellectual Property: HHS Reference No. E–552–2013/0—U.S. Provisional Patent Application No. 61/908,861 filed November 26, 2013.

Licensing Contact: Suryanarayana Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov.*

Novel Epstein-Barr Virus Vaccines

Description of Technology: Epstein-Barr Virus (EBV) is the causative agent of infectious mononucleosis and is associated with certain types of cancers, such as Hodgkin's lymphoma, Burkitt's lymphoma, gastric carcinoma, and nasopharyngeal carcinoma. There are currently no vaccines against EBV on the market and there is only supportive treatment available for EBV infection.

The subject technologies are novel vaccine candidates against EBV that employ fusion proteins consisting of immunogenic portions of the EBV envelope glycoproteins (i.e. gp350, gH/gL, etc.) that are found on the surface of the virus fused with a self-assembling protein such as ferritin. The fusion proteins multimerize and the resulting nanoparticles serve as the antigens in the vaccine. In mice, these vaccine candidates were able to elicit neutralizing antibodies that were significantly higher than vaccination with only soluble forms of the EBV envelope glycoproteins lacking the self-assembly domains. In some cases, the fusion protein vaccine candidates were able to elicit neutralizing antibodies while vaccination with the corresponding soluble versions elicited primarily non-neutralizing antibodies. These neutralizing antibody titers in immunized mice were substantially higher than those seen in humans naturally infected with EBV.

Potential Commercial Applications: Vaccines against EBV.

Competitive Advantages: The subject technologies are novel vaccine candidates against EBV that were able to elicit significantly higher levels of neutralizing antibodies than vaccines based solely on soluble forms of the EBV envelope glycoproteins lacking self-assembly domains.

Development Stage

- Early-stage
- In vitro data available
- In vivo data available (animal)

Inventors: Masaru Kanekiyo, Wei Bu, Jeffrey Cohen (all of NIAID).

Intellectual Property

- HHS Reference No. E–531–2013/0–US–01—U.S. Provisional Patent Application No. 61/889,840 filed 11 Oct 2013
- HHS Reference No. E–531–2013/1–US–01—U.S. Provisional Patent Application No. 61/921,284 filed 27 Dec. 2013

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; *changke@mail.nih.gov.*

Lentiviral Vectors To Modulate p53 Function in Human Stem Cells

Description of Technology: The tumor suppressor protein p53 regulates the self-renewal and pluripotency of normal and cancer stems cells, as well as the efficiency of reprogramming normal cells into induced pluripotent stem cells (iPSC). Natural human p53 isoforms delta133p53 and p53beta are the physiological inhibitor and enhancer, respectively. Researchers at the National Cancer Institute, NIH, have discovered that human embryonic stem cells (hESC) express delta133p53 protein much more abundantly than normal human fibroblasts or cancer cell lines.

Available for licensing are lentiviral vectors for constitutive over-expression of the p53 isoforms delta133p53 and p53beta, inducible over-expression of delta133p53, and inducible shRNA knock-down of delta133p53.

Potential Commercial Applications

- Stem cell-based regenerative medicine for the treatment of age-related degenerative diseases.
- Targeting of cancer stem cells for treatment of cancer.
- Development of compounds that mimic the effects of the p53 isoforms on hESC and iPSC.
- Development of compounds that act in p53 isoform-dependent manners to regulate self-renewing vs. asymmetric cell divisions in cancer stem cells.

Competitive Advantages

- Enhanced expression of delta133p53 for efficient hESC self-renewal and pluripotency without genome instability.
- Enhanced expression of delta133p53 for efficient reprogramming to iPSC without genome instability.
- Enhanced expression of p53beta and/or knockdown of delta133p53 for efficient induction of hESC/iPSC differentiation without unwanted cell death.

Development Stage: In vitro data available.

Inventors: Curtis C. Harris, et al. (NCI).

Publication: Fujita K, et al. Positive feedback between p53 and TRF2 during telomere-damage signalling and cellular senescence. Nat Cell Biol. 2010 Dec;12(12):1205–12. [PMID 21057505].

Intellectual Property: HHS Reference No. E–137–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Related Technology: HHS Reference No. E–239–2010/0—Retroviral and Lentiviral Vectors to Increase Efficiency of Inducible Pluripotent Stem Cell (iPSC) Production.

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

Dated: August 6, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–18853 Filed 8–8–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be open to the public, the attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: September 5, 2014.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate reports from the HeLa Genome Data Access and the Stem Cell working groups.

Place: National Institutes of Health (Telephone Conference Call), Dial in 800–779–9282, Passcode: ACD Teleconference.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *woodgs@od.nih.gov.*

Any member of the public interested in presenting oral comments to the committee must notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations must submit a letter of intent, a brief description of the organization represented, and a short