

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3792 .....	9	1	9	0.5 (30 minutes)	4.5

<sup>1</sup> There are no capital costs or operating maintenance costs associated with this collection of information.

Respondents to this proposed collection of information would be manufacturers of biosimilar biological product candidates. Based on FDA's database system, there are an estimated 18 manufacturers that fall into this category. However, not all manufacturers will have submissions in a given year and some may have multiple submissions. FDA estimates 9 annual responses that include the following: 6 INDs or BPD meetings, 2 applications, and 1 supplement. The estimated hours per response are based on FDA's past experience with other submissions, which average 30 minutes.

Dated: June 12, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-14740 Filed 6-15-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

[Docket Number OIG-1301-N]

### Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice and Opportunity for Comment.

**SUMMARY:** This **Federal Register** notice informs the public that OIG: (1) Intends to update the Provider Self-Disclosure Protocol (63 FR 58399, October 30, 1998) and (2) solicits input from the public for OIG to consider in updating the Protocol.

**DATES:** To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on August 17, 2012.

**ADDRESSES:** In commenting, please refer to file code OIG-1301-N. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific

recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Kenneth D. Kraft, Office of Inspector General, Department of Health and Human Services, Attention: OIG-1301-N, Room 5541B, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Kenneth D. Kraft, Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff at (202) 708-9848.

All submissions must include the agency name and docket number for this **Federal Register** document. All comments, including attachments and other supporting material received, are subject to public disclosure.

**FOR FURTHER INFORMATION CONTACT:**

Kenneth D. Kraft, Department of Health and Human Services, Office of Inspector General, Office of External Affairs, at (202) 708-9848.

**SUPPLEMENTARY INFORMATION:** *Inspection of Public Comments:*

All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> after they have been received. Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 708-9848.

*Background:* In 1998, OIG published the Provider Self-Disclosure Protocol (the Protocol) to establish a process for health care providers to disclose potential fraud involving the Federal health care programs. The Protocol provides guidance on how to investigate this conduct, quantify damages, and report the conduct to OIG to resolve the provider's liability exposure under OIG's civil money penalty (CMP) authorities. Over the past 14 years, we have resolved over 800 disclosures, resulting in recovering over \$280 million to the Federal health care programs. Through our experience in resolving Protocol matters, we identified areas where additional guidance would be beneficial to the provider community and would improve the efficient resolution of Protocol matters. Specifically, we issued three Open Letters to Health Care Providers to address some of these issues. First, in 2006 we announced an initiative to encourage disclosure of conduct creating liability under OIG's anti-kickback and physician self-referral law CMP authorities. In 2008, we issued additional guidance and requirements for Protocol submissions to increase the efficiency of the Protocol, including new requirements for the initial submission and specific time commitments from the provider. This Open Letter also announced the presumption of not requiring a compliance agreement as part of settling a cooperative and complete disclosure. Finally, in 2009, we stated we would no longer accept disclosure of a matter into the Protocol that involved only liability under the physician self-referral law in the absence of a colorable anti-kickback violation. We also announced a minimum \$50,000 settlement amount for kickback-related submissions.

After over a decade of experience in resolving Protocol disclosures, we are considering revising the Protocol to provide additional guidance. We are soliciting comments, recommendations, and other suggestions from concerned parties and organizations on how best to revise the Protocol to address relevant issues and to provide useful guidance to the health care industry.

Dated: June 8, 2012.

**Daniel R. Levinson,**

*Inspector General.*

[FR Doc. 2012-14585 Filed 6-15-12; 8:45 am]

BILLING CODE 4152-01-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.

#### Endothelial Cell Line To Study Prevention of Atherosclerosis

**Description of Technology:** Atherosclerosis underlies most cases of cardiovascular disease (CVD), which is now the major cause of morbidity and mortality in developed countries. An inflammatory reaction is an essential component in the appearance and development of an atherosclerotic lesion. The inflammatory process is associated with the expression of adhesion molecules such as vascular cell adhesion molecule (VCAM) at the surface of endothelial cells. Antiatherogenic lipoprotein, high density lipoprotein (HDL), is known to down regulate the expression of VCAM. Increasing levels of HDL is a promising way to reduce the risk of CVD.

This technology is directed to the generation of a stable endothelial cell line expressing a luciferase reporter construct driven by the VCAM

promoter. This reporter system enables an easier measurement of VCAM expression and determination of the effect of HDL on endothelial cell inflammation. This technology can be used to screen for the effect of drugs that modulate HDL metabolism and it is more convenient than doing Western blots.

**Potential Commercial Applications:**

- Study of prevention of atherosclerosis
- Screen serum for the effect of HDL on endothelial cell inflammation
- Screen for the effect of drugs that modulate HDL metabolism

**Competitive Advantages:**

- Easy monitoring of down regulation of VCAM with luciferase
- More convenient than doing Western blots

**Development Stage:** In vitro data available.

**Inventor:** Alan T. Remaley (NHLBI).

**Publication:** D'Souza W, *et al.*

Structure/function relationships of apolipoprotein a-I mimetic peptides: Implications for antiatherogenic activities of high-density lipoprotein. *Circ Res.* 2010 Jul 23;107(2):217-27. [PMID 20508181].

**Intellectual Property:** HHS Reference No. E-149-2012/0—Research Tool. Patent protection is not being pursued for this technology.

**Licensing Contact:** Fatima Sayyid, M.H.P.M.; 301-435-4521; [Fatima.Sayyid@nih.hhs.gov](mailto:Fatima.Sayyid@nih.hhs.gov).

**Collaborative Research Opportunity:** The Cardiovascular & Pulmonary Branch, NHLBI/NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize endothelial cells to study prevention of atherosclerosis. For collaboration opportunities, please contact Dr. Alan Remaley at [aremaley1@cc.nih.gov](mailto:aremaley1@cc.nih.gov).

#### Software for Modeling Tumor Delivery and Penetration of Antibody-Toxin Anti-Cancer Conjugates

**Description of Technology:** Available for licensing is software for modeling permeability and concentration of intravenously administered antibody anti-cancer agent conjugates in solid tumor. The models can be used to determine optimal dosing regimen of a therapeutic in a particular cancer type. Thirty factors that affect delivery rates and efficiencies are analyzed as variables in generating the models.

**Potential Commercial Applications:**

- Drug Design
  - Combination Therapy
  - Personalized Medicine
- Competitive Advantages:**

- Accurate permeability modeling of anti-cancer therapeutics
  - Personalized Medicine
- Development Stage:**
- Early-stage
  - Pre-clinical
- Inventors:** Byungkook Lee (NCI), Youngshang Pak (EM), Ira Pastan (NCI).  
**Publications:**

1. Fujimori K, *et al.* A modeling analysis of monoclonal antibody percolation through tumors: a binding-site barrier. *J Nucl Med.* 1990 Jul;31(7):1191-1198. [PMID 2362198]
2. Jain RK. Delivery of molecular and cellular medicine to solid tumors. *Adv Drug Deliv Rev.* 2001 Mar 1;46(1-3):149-168. [PMID 11259838]
3. Thurber GM, *et al.* Antibody tumor penetration: transport opposed by systemic and antigen-mediated clearance. *Adv Drug Deliv Rev.* 2008 Sep;60(12):1421-1434. [PMID 18541331]
4. Li Y, *et al.* Delivery of nanomedicines to extracellular and intracellular compartments of a solid tumor. *Adv Drug Deliv Rev.* 2012 Jan;64(1):29-39. [PMID 21569804]
5. [http://www.accelereyes.com/examples/drug\\_delivery\\_model](http://www.accelereyes.com/examples/drug_delivery_model)
6. Pak Y, *et al.* Antigen shedding may improve efficiencies for delivery of antibody-based anticancer agents in solid tumors. *Can Res.* 2012 May 4; Epub ahead of print, doi: 10.1158/0008-5472.CAN-11-3925. [PMID 22562466]

**Intellectual Property:** HHS Reference No. E-060-2012/0—Software. Patent protection is not being pursued for this technology.

**Licensing Contact:** Michael Shmilovich; 301-435-5019; [mish@codon.nih.gov](mailto:mish@codon.nih.gov).

**Collaborative Research Opportunity:** The NCI, CCR, Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize targeted delivery of anti-cancer agents in solid tumors. For collaboration opportunities, please contact John Hewes, Ph.D. at [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov).

#### Mouse Model of STAT5 for the Drug Screen and the Research of Cancer and Autoimmunity

**Description of Technology:** The invention is a STAT5 mutant mouse that can be used in research related to cancer, autoimmunity and infectious diseases as well as drug screening. The mouse model itself has multiple immunological defects resulting in formation of STAT5 dimers but not tetramers.