attitudes (because this is not needed in an experimental design and we are using a fictitious drug for the stimulus materials), or (7) get industry approval and public comment on the mocked up ads.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
21 U.S.C. 393(b)(2)(c) Screener, pretesting	1,600	1	1,600	.03	48
21 U.S.C. 393(b)(2)(c) Questionnaire, pretesting	800	1	800	.16	128
21 U.S.C. 393(b)(2)(c) Screener, study	4,800	1	4,800	.03	144
21 U.S.C. 393(b)(2)(c) Questionnaire, study	2,400	1	2,400	.25	600
Total					920

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

Dated: December 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–31057 Filed 12–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Women's Health Initiative Observational 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 Heart, Lung, and Blood Institute (NHLBI), 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.

Proposed Collection: Title: The Women's Health Initiative (WHI) Observational Study. *Type of Information Collection Request:* Revision OMB #0925–0414. *Need and Use of Information Collection:* This study will be used by the NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. Continuation of follow-up for ascertainment of medical history update forms will provide essential data for outcomes assessment for this population of aging women. *Frequency of Response:* Annually. *Affected Public:* Individuals or households and health care providers. *Type of Respondents:* Individuals or households; health care providers. The annual reporting burden is as follows:

ESTIMATE OF ANNUAL HOUR BURDEN

Type of response	Number of respondents	Frequency of response	Average hours per response	Annual hour burden
Observational Study Participants	63,230	1.1	.338	23,509
Next of Kin[1]	1163	1	.083	97
Health Care Providers[1]	9	1	.083	.77
Total	64,402			23,607

[1] Annual burden is placed on health care providers and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.

The annualized cost to respondents is estimated at $377,725, assuming respondents time at the rate of $16 per hour and physician time at the rate of $50 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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 Ms. Shari Eason Ludlam, MPH, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892–7934, or call non-toll-free number 301–402–2900 or E-mail your request, including your address to: *Ludlams@nhlbi.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.

Dated: December 16, 2008.

Michael S. Lauer,

Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Dated: December 16, 2008.

Suzanne Freeman,

Chief, FOIA, NHLBI, National Institutes of Health.

[FR Doc. E8–30848 Filed 12–29–08; 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.

Doxycycline-Inducible B16 Melanoma Cell Lines Expressing CXCR4 or CCR10

Description of Technology: The chemokine receptor CXCR4 functions in normal cells, but has been shown to be the most common chemokine receptor expressed on cancer cells, including melanoma, colon, breast, and lung cancers. It plays roles in angiogenesis and cancer cell survival as well as metastasis. CCR10 has also been shown to be expressed by melanoma cells. Like CXCR4, expression of CCR10 can enhance cancer cell survival and block immune recognition of cancer cells. Antagonists of CXCR4 and CCR10, under various conditions, have decreased metastasis or prevented tumor formation after implantation of cancer cells in mice.

These cell lines are based on the widely used B16 murine melanoma cell line. The cell lines were transduced with retroviral vectors encoding cDNA for either CXCR4 or CCR10 under control of a TET-dependent promoter. Both lines achieve greater than 10 fold induction of the respective genes (proteins), which has been confirmed by surface antibody staining using flow cytometry. These cell lines are ideally suited for studying the effect of these chemokine receptors in tumor growth or metastasis. They are also useful for developing a mouse model for studying the effect of down-regulating these receptors specifically in melanoma cells. This would mimic the effect of antagonists without the confounding effects of systemically inhibiting CXCR4 or CCR10. By either adding or removing dietary administered doxycycline, receptor expression can be regulated to assess the role of these two receptors in a variety of cancer-related assays.

Applications:

- Study the effect of chemokine receptors in tumor growth or metastasis
- Test CXCR4 and CCR10 antagonists in preclinical studies
- Develop B16 melanoma mouse model mimicking the effect of chemokine receptor antagonists

Advantages:

- Ability to regulate *in vitro* and *in vivo* expression of the chemokine receptor
- Ability to investigate the *in vivo* role in cancer cells of doxycycline control of chemokine receptor expression

Market: Cancer is the second leading cause of death in the U.S. and it is estimated that more than 1 million Americans develop cancer in a year.

Development Status: The technology is currently in the preclinical stage of development.

Inventors: Sam T. Hwang (NCI) .

Publication: T Kakinuma, ST Hwang. Chemokines, chemokine receptors, and cancer metastasis. J Leukoc Biol. 2006 Apr;79(4):639–651.

Patent Status: HHS Reference No. E–345–2008/0—Research Material. Patent protection is not being sought for either technology.

Licensing Status: Available for non-exclusive licensing under a Biological Materials License Agreement.

Licensing Contact: Adaku Nwachukwu, J.D.; 301–435–5560; *madua@mail.nih.gov*.

Monoclonal Antibodies to the Tumor-Specific Antigen, Human ROR1

Description of Technology: B–cell chronic lymphocytic leukemia (B–CLL) is an incurable disease developed by more than 15,000 Americans each year and currently, there are no therapeutic monoclonal antibodies (mAbs) that specifically recognize B–CLL tumor cells. Receptor tyrosine kinase-like orphan receptor 1 (ROR1) is a constitutively expressed tumor-specific cell surface antigen and an ideal target for therapeutic antibodies.

Available for licensing are four mouse anti-human ROR1 mAbs (hybridomas designated 2A2, 2D11, 1A1, and 1A7). All four mAbs bind specifically to the extracellular domain of human ROR1 and have good potential for therapeutic development by either humanization, conversion to chimeric mouse/human antibodies, or conjugation to a radioisotope, chemical drug or bacterial toxin.

Applications:

- Therapeutic antibodies against ROR1-expressing cancers like B–CLL and possibly other hematologic and solid malignancies
- Research tools for the study of ROR1 in cancer biology

Advantages:

- Hybridomas provide a continuous source of mAb
- Target extracellular domain of ROR1

Market:

- Currently, mAbs alemtuzumab® and rituximab®, which are not tumor cell-specific, are used for treating B–CLL. Rituximab® generated sales of 5.2 billion U.S. dollars in 2007.
- MAb market is estimated to be worth $30.3 billion in 2010 and it is one of the fastest growing sectors of the pharmaceutical industry with a 48.1% growth rate between 2003 and 2004.

Inventors: Christoph Rader and Sivasubramanian Baskar (NCI).

Publication: S Baskar et al. Unique cell surface expression of receptor tyrosine kinase ROR1 in human B-cell