DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Proposed Collection; Comment Requested; Study to Improve Thyroid Doses From Fallout Exposure in Kazakhstan—Follow-up

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, National Cancer Institute (NCI), 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: Study to improve thyroid doses from fallout exposure in Kazakhstan—Follow-up, Radiation Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute (NCI). The proposed work builds on an existing study conducted 1998 of radiation exposure and thyroid disease among individuals in Kazakhstan exposed during childhood to radioactive fallout from nuclear tests conducted at the Semipalatinsk Nuclear Test Site (SNTS) between 1949 and 1962. The 1998 study recruited 3000 participants who were 21 years of age or younger at fallout exposure, from eight villages. Analyses of preliminary dose estimates suggest that internal and external exposures independently and significantly contributed to the dose response for thyroid nodules. *Type of Information Collection Request:* NEW.

This study population in Kazakhstan is unique in several ways. This is only the fourth major population in which dose-response has been studied for thyroid disease associated with environmental releases of radioactive materials. The conditions of fallout exposure in Kazakhstan are directly relevant to conditions following a hypothetical nuclear accident or a terrorist attack involving high levels of local fallout. Among large study populations with high exposure following environmental releases of radioactive materials, this population is second in size only to those most heavily exposed to radioactive materials released during the 1986 Chornobyl reactor accident. However, unlike the Chornobyl population, the Kazakhstan population was exposed to high levels of radiation from external as well as internal sources. This allows us to evaluate the relative effectiveness of internal and external radiation exposures in terms of thyroid disease risk within a single population. *Need and Use of Information Collection:* NCI proposes a small-scale field study to acquire new data to improve our estimates of internal and external radiation dose and thereby refine the dose-response estimates. Retrospective information about factors influencing radiation dose to the thyroid gland in children of two distinct ethnic groups (Kazakh and Russian) will be collected using focus group interviews. These new collected data will address key weaknesses in the current dosimetry, including milk and milk product consumption, time typically spent outdoors, radiation shielding provided by dwellings and other buildings, and seasonal practices of pasturing and supplemental feeding of dairy animals at the time of the nuclear tests. Since the objective is to estimate group-specific mean values (and ranges) and not to collect individual data, focus groups are better suited than conventional in-depth individual interviews.

Focus group members for each village will consist of two sets of participants who (i) speak Russian or Kazakh and are able to participate in a 2 hour focus group session, and (ii) have verified history of residence in the village at the time of the nuclear tests will be recruited for the study.

Frequency of Response: Once;

Affected Public: Individual and household.

Type of Respondent: Women, Men age 65 or older

Estimated Number of Respondents: 128.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours per Response: 2.0. Annual Burden Hours Requested: 256.

- Women: In each village, three groups of 8 women ages 65 years and older who had children less than age 15 years or provided care to children in this age group (i.e., younger siblings, nieces and nephews) at the time of the nuclear tests.
- Men: In each village, 8 men ages 65 and older who were engaged in farming and care of dairy animals at the time of the nuclear tests.

Since the main exposure years (time of the tests) varies by village, specific eligibility requirements will be applied to each village. Verification of residence history will be based on regional records.

TABLE A.—TOTAL BURDEN ESTIMATES FOR DATA COLLECTION

Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Focus Group	128	1	2 hours	256
Male	32	1	2 hours	64
Female	96	1	2 hours	192
Total				256

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 proposed performance of the functions of the agency, including whether the information shall 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 Charles Land, Project Officer, National Cancer Institute, EPS , 6120 Executive Boulevard MSC 7238, Bethesda, Maryland 20852, or call non-toll free number 301–594–7165 or FAX your request, including your address to 301–402–0207.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 60 days of this publication.

Dated: January 8, 2007.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

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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.

Novel Benztropine Analogs for Treatment of Cocaine Abuse and Other Mental Disorders

Description of Technology: Dopamine is a neurotransmitter that exerts important effects on locomotor activity, motivation and reward, and cognition. The dopamine transporter (DAT) is expressed on the plasma membrane of dopamine synthesizing neurons, and is responsible for clearing dopamine released into the extra-cellular space, thereby regulating neurotransmission. The dopamine transporter plays a significant role in neurotoxicity and human diseases, such as Parkinson's disease, drug abuse (especially cocaine addiction), Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder (ADD/ADHD), and a number of other CNS disorders. Therefore, the dopamine transporter is a strong target for research and the discovery of potential therapeutics for the treatment of these indications.

This invention discloses novel benztropine analogs and methods of using these analogs for treatment of mental and conduct disorders such as cocaine abuse, narcolepsy, ADHD, obesity and nicotine abuse. The disclosed analogs are highly selective and potent inhibitors of DAT, but without an apparent cocaine-like behavioral profile. In addition to their use as a treatment for cocaine abuse, these compounds have also shown efficacy in animal models of ADHD and nicotine abuse, and have also been shown to reduce food intake in animals. They may also be useful medications for other indications where dopamine-related behavior is compromised, such as alcohol addiction, tobacco addiction, and Parkinson's disease.

Applications: Drug leads for treatment of cocaine abuse, ADHD, nicotine abuse, obesity, and other dopamine-related disorders; Imaging probes for dopamine transporter binding sites.

Development Status: Pre-clinical data are available.

Inventors: Amy H. Newman, Mu-fa Zou, and Jonathan L. Katz (NIDA).

Patent Status: U.S. Provisional Application No. 60/710,956 filed 24 Aug 2005 (HHS Reference No. E–234–2005/0–US–01); PCT Application No. PCT/US2006/33103 filed 24 Aug 2006 (HHS Reference No. E–234–2005/1–PCT–01 and HHS Reference No. E–129–2006/0).

Licensing Status: Available for exclusive or nonexclusive licensing.

Licensing Contact: Tara Kirby, Ph.D.; 301/435–4426; *tarak@mail.nih.gov*.

Collaborative Research Opportunity: The Medicinal Chemistry and Psychobiology Sections, National Institute on Drug Abuse-Intramural Research Program, National Institutes of Health, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize medications to treat cocaine abuse and addiction. Please contact John D. Hewes, Ph.D. at 301/435–3121 or *hewesj@mail.nih.gov* for more information.

Protein Arginine N-methyltransferase 2 (PRMT–2), a Modulator of NFKB, E2F1, and STAT3 Activity

Description of Technology: Protein-arginine methyltransferases (PRMTs) contain methyltransferase domains that modify chromatin and regulate cellular transcription through the post-translational methylation of arginine residues on the guanidine group of target proteins. Members of this family have roles in RNA processing, transcriptional regulation, signal transduction, and DNA repair. Until recently, the functional significance of one member of this family, PRMT–2, was unknown.

Researchers at NHLBI, led by Dr. Elizabeth Nabel, have elucidated the role of PRMT–2. They have found that PRMT–2 modulates the activity of NFKB, E2F1, and STAT3. PRMT–2 inhibits NFKB dependent transcription, and therefore PRMT–2 has a role in modulating inflammation and the immune response. Also, PRMT–2 proteins can repress E2F1 transcriptional activity and cause cell cycle arrest, and thus may be used to treat or prevent cancer. PRMT–2 also methylates STAT3, and inhibition or loss of PRMT–2 function causes mammals to lose weight, eat less and become more sensitive to insulin.

The invention describes methods of modulating PRMT–2 activity or expression in cells. These methods can be used to inhibit the function of NF?B, E2F1 and STAT3 for treatment of a number of disorders, including inflammation, cancer, and diabetes.

Applications: Target for treatment and study of a number of disorders, including:

Diabetes, obesity and metabolic syndrome diseases; Inflammation and immune response-related disorders; Cancer.

Inventors: Elizabeth Nabel (NHLBI), Hiroaki Iwasaki (NHLBI), Takanobu Yoshimoto (NHLBI), and Gary Nabel (NIAID).

Patent Status: U.S. Provisional Application No. 60/466,751 filed 30 April 2003 (HHS Reference No. E–190–2003/0–US–01); PCT Application No. PCT2004/013375 filed 30 April 2004, which published as WO 2004/098634 on 18 Nov 2004 (HHS Reference No. E–190–2003/0–PCT–02); U.S. Application No. 11/263,657 filed 31 Oct 2005, which published as WO 2006/0239990 on 26