Proposed Project: Health Resources and Services Administration Core Clinical Measures Implementation Feasibility Study

In response to the Health and Human Service's Department-wide objectives and HRSA's strategic goals, a set of core clinical performance measures have been established. These measures will assist in the evaluation of HRSA program performance in defined clinical areas to facilitate quality improvement activities for HRSA and its grantees. The purpose of the proposed voluntary feasibility study is to learn from HRSA's health service delivery grantees, which have different reporting capacities, about their abilities to report national standardized measures. More specifically, the study will help HRSA to understand: (1) The factors involved in the HRSA grantee decision making processes around measure selection/choice; (2) Grantees' data collection capacity including tools, processes and infrastructure; (3) Level of grantee effort involved in measure reporting; and (4) How the performance process will impact the grantees' quality improvement efforts. Overall the feasibility study will allow HRSA to query its grantees related to the newly introduced core clinical performance measure set.

The feasibility study includes the actual data collection of the proposed clinical measures along with a report form to assess burden, data collection and reporting capacity, and technical assistance needs. Additionally, the study will provide HRSA with the opportunity to refine instructions and performance measure definitions accordingly in preparation for the actual implementation of the clinical measures.

The estimated annualized response burden is as follows:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Clinical Measures	50	1	50	40	2,000
Report Form	50	1	50	1.5	75
Total	50		50		2075

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 8, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–19377 Filed 11–15–06; 8:45 am]

BILLING CODE 4165–15–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.

Second Generation Nitric Oxide-Releasing Non-Steroidal Anti-Inflammatory Drugs Possessing a Diazeniumdiolate Group (NONO–NSAIDs)

Description of Technology: Non-steroidal anti-inflammatory drugs (NSAIDs) are one of the most useful clinical therapies for the treatment of pain, fever and inflammation. It is estimated that more than 30 million people take NSAIDs every day. However, the major mechanism by which NSAIDs exert their anti-inflammatory activity is also responsible for the gastrointestinal, renal and hepatic side effects observed in patients undergoing long-term treatment of chronic conditions. The most common side effects associated with NSAID administration are gastroduodenal erosions and ulcerations affecting around 15% of chronic NSAID users. While many of these clinical manifestations are mild, they may develop into serious events such as bleeding, perforation, obstruction, and sudden death. Therefore, the gastric irritant effect of NSAIDs (particularly aspirin) can be a deterrent to its long-term use for the prophylactic prevention of adverse cardiovascular events such as stroke and myocardial infarction, or as a safe chemopreventive agent to avoid the recurrence of colorectal cancer (CRC).

One of the main strategies that have emerged to improve the safety profile of NSAIDs is the linkage of a nitric oxide (NO)-releasing moiety to the structure of classical NSAIDs (NO–NSAIDs). However, all NO-releasing NSAIDs published so far have a nitrooxyalkyl group as the NO-releasing group. An important drawback to this design is the fact that production of NO (only one equivalent) from organic nitrate esters requires a metabolic three-electron reduction *in vivo*, and this activation decreases in efficiency on continued use of the drugs, contributing to ''nitrate tolerance''.

This invention describes the design, synthesis and biological evaluation of novel NO-releasing non-steroidal anti-inflammatory prodrugs (NONO–NSAIDs) possessing a *N*-diazen-1-ium-1,2-diolate (NONOate), which offers additional advantages compared with organic nitrate-based NO–NSAIDs:

(a) Simultaneous release of the corresponding NSAID and NO.

(b) Production of two equivalents of NO (twice as much) by a first-order rate.

(c) Metabolic activation (hydrolysis) mediated by non-specific esterases, which unlike redox metabolism, is not expected to produce tolerance upon long-term treatment.

Applications: This invention provides a group of anti-inflammatory, analgesic, and gastrointestinal safe prodrugs, which are expected to be a suitable alternative for the prophylactic prevention of adverse cardiovascular

events such as stroke and myocardial infarction, as well as cancer chemoprevention.

Market: (1) An estimated 60 million people in the United States use NSAIDs regularly; (2) An estimated $5 billion are spent each year in the United States on prescription NSAIDs and approximately $2 billion are spent on over-the-counter NSAIDs.

Development Status: Pre-clinical data is available.

Inventors: Carlos Velazquez Martinez (*NCI*) *et al.*

Related Publication: C Velazquez, PN Praveen Rao, EE Knaus. Novel nonsteroidal anti-inflammatory drugs possessing a nitric oxide donor diazen-1-ium-1,2-diolate moiety: Design, synthesis, biological evaluation, and nitric oxide release studies. J Med Chem. 2005 Jun16;48(12):4061–4067.

Patent Status: U.S. Provisional Application 60/794,421 filed 24 Apr 2006 (HHS Reference No. E–186–2006/0–US–01).

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Norbert Pontzer, PhD, J.D.; 301/435–5502; *pontzern@mail.nih.gov.*

Collaborative Research Opportunity: The Chemistry Section of the Laboratory of Comparative Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the prodrugs described, as new and safer analgesic, anti-inflammatory, anti-thrombotic, and cancer chemopreventive agents. Please contact Betty Tong, Ph.D. at 301–594–4263 or *tongb@mail.nih.gov* for more information.

Rat or Mouse Exhibiting Behaviors Associated With Human Schizophrenia

Description of Technology: A newly developed animal model for schizophrenia is valuable for assaying pharmaceutical compounds for treating this disorder. Schizophrenia is a neuropsychiatric disorder characterized by cognitive deficits, bizarre behavior and/or hallucinations. Presently, there has been no satisfactory animal model for testing promising therapies for this disorder.

This invention provides a unique and surprisingly accurate animal model for human schizophrenia. The animals are brain damaged while prepubescent. The brain damage consists of a ventral hippocampus lesion induced by exposure of the hippocampus region to a neurotoxin. When the animal reaches puberty, abnormal behavior and a number of biological phenomena associated with schizophrenic symptoms emerge.

The present invention also provides methods of assaying the anti-schizophrenic potential of pharmaceutical compositions. The methods involve (a) Inducing or creating a lesion in the ventral hippocampus of a prepubescent mammal, (b) nurturing or raising the mammal until postpuberty, (c) administering to the mammal a pharmaceutical composition thought to have anti-schizophrenic properties; and (d) determining the mammal's response to the pharmaceutical composition. The anti-schizophrenic potential of the pharmaceutical composition is assessed by objectively measuring the mammal's behavior following administration of the pharmaceutical composition. The behaviors which are measured typically include the following: locomotor activity in a cage, in unfamiliar or novel environments, after injection or administration of drugs (*e.g.*, amphetamines), after mild electric shock, after exposure to sensory stimuli (*e.g.*, noise), in water (swim test), after immobilization, in social interactions, and in various learning and reward paradigms.

The neurotoxin used can be selected from a number of known agents which lethally affect neurons usually, but not exclusively, by over-exciting their glummate receptors. Examples of such neurotoxins include ibotenic acid, N-methyl-D-aspartic acid, kainic acid, dihydrokainate, DL-homocysteate, L-cysteate, L-aspartate, L-glutamate, colchicine, ferric chloride, omega-conotoxin GVIA, 6-hydroxy-dopamine.

Advantage: This is the first model showing postpubertal emergence of abnormalities similar to those reported in schizophrenia.

Applications: (1) Animal model for human schizophrenia; (2) Screening methods for Anti-schizophrenics.

Development Status: Validated, well characterized and ready for use.

Inventors: Daniel R. Weinberger, Barbara K. Lipska, and George E. Jaskiw (NIMH).

Publications:

1. AHC Wong, BK Lipska, O Likhodi, E Boffa, DR Weinberger, JL Kennedy, HHM Van Tol. Cortical gene expression in the neonatal ventral-hippocampal lesion rat model. Schizophr Res. 2005 Sep 15;77(2–3):261–270.

2. BK Lipska. Using animal models to test a neurodevelopmental hypothesis of schizophrenia. J Psychiatry Neurosci. 2004 Jul;29(4):282–286.

3. BK Lipska and DR Weinberger. To model a psychiatric disorder in animals: schizophrenia as a reality test. Neuropsychopharmacology 2000 Sep;23(3):223–239.

4. BK Lipska, GE Jaskiw, DR Weinberger. Postpubertal emergence of hyperresponsiveness to stress and to amphetamine after neonatal excitotoxic damage: a potential animal model of schizophrenia. Neuropsychopharmacology 1993 Aug;9(1):67–75.

Patent Status: U.S. Patent No. 5,549,884 issued 27 Aug 1996 (HHS Reference No. E–013–1993/0–US–01).

Availability: Available for non-exclusive licensing.

Licensing Contact: Norbert Pontzer, Ph.D., J.D.; 301/435–5502; *pontzern@mail.nih.gov.*

Dated: November 8, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–19408 Filed 11–15–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; ENCODE RFA.

Date: December 6–7, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Rudy O. Pozzatti, PhD, Scientific Review Administrator, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301 402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)