

assessment of histological and serological endpoints.

I. Participation in the Public Workshop

There is no fee to attend the public workshop, but attendees must register in advance. Space is limited and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at <http://www.great3.org> before March 1, 2015. For those without Internet access, please contact Kelly Richards (see **FOR FURTHER INFORMATION CONTACT**) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Kelly Richards (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

II. Transcripts

Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and on the Internet at <http://www.regulations.gov> approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD-ROM after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Fax requests to 301-827-9267.

Dated: January 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-01625 Filed 1-28-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIH)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 21, 2014, volume #79, page 69500 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit

comments in writing, or request more information on the proposed project, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301-435-0941 or Email your request, including your address to curriem@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIH), 0925-0648, Expiration Date 1/31/2015, EXTENSION, National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: There are no changes being requested for this submission. The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. This generic will provide information about the NIH Institutes and Centers customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. It will also allow feedback to contribute directly to the improvement of program management. Feedback collected under this generic clearance will provide useful information but it will not yield data that can be generalized to the overall population.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated burden hours are 49,358.

Estimated Annualized Burden Hours

ESTIMATED ANNUAL REPORTING BURDEN

Type of collection	Number of respondents	Annual frequency per response	Hours per response	Total annual burden hours
Customer Satisfaction Surveys	1,000	1	30/60	500
In-Depth Interviews (IDIs) or Small Discussion Groups	1,000	1	90/60	1,500
Focus Groups	1,000	1	90/60	1,500
Usability and Pilot Testing	150,000	1	5/60	12,525
Conference/Training—Pre and Post Surveys	100,000	2	10/60	33,333

Dated: January 22, 2015.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2015-01685 Filed 1-28-15; 8:45 am]

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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, 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.

Miniature System for Manipulating Small Animals in High-Throughput Screening Small Molecules

Description of Technology: The invention pertains to a miniaturized plating and feeding system based on a 96-well microplate base and is intended to reduce manipulation of organisms as well as amounts of test drug/anesthetic, thereby mitigating waste. The kit comprises a feeder plate, transfer adaptor and receiver plate. The feeder plate is defined by, for example, a plastic 96-well plate with rounded wells. The rounded bottoms can dispense to or permit access to the test organism of liquid food or drug through about 7 holes of approximately 350 microns in diameter. A top portion of the well provides test organisms (e.g., drosophila, daphnia) with sufficient

space to enjoy normal life-cycles without confinement stress. The feeder plate includes means for interfacing with complementary components of the transfer and receiver plates through receiving holes and complementary dowels or pins. A transfer adapter allows the interconnection of the feeder plate to the receiver plate. The transfer plate can be configured to be square or rounded for the transfer of organisms from the feeder plate to the receiver plate.

Potential Commercial Applications

- Drug Development
- Toxicity Studies
- Drug Design

Competitive Advantages

- Small animals
- High Throughput
- Space efficiency
- Resource economy

Development Stage

- Early stage
- Prototype

Inventors: Maria De Los Angeles Jaime and Brian Oliver (NIDDK).

Intellectual Property: HHS Reference No. E-034-2015/0—US Provisional Application No. 62/080,181 filed November 14, 2015.

Licensing Contact: Michael Shmilovich, Esq.; 301-435-5019; shmilovm@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 High-Throughput Small Animal Manipulation for Drug Design. For collaboration opportunities, please contact Marguerite J. Miller at miller marg@nidk.nih.gov.

LRKK2 Inhibitors: Novel Treatment for Intestinal Bowel Disorders

Description of Technology: Use of Leucine Rich Repeat Kinase 2 (LRRK2) inhibitors for the treatment of Intestinal Bowel Disorders (IBD) is disclosed. IBD is a broad term that describes conditions with chronic or recurring immune response and inflammation of the gastrointestinal tract. Crohn's disease and ulcerative colitis, two common forms of idiopathic IBD, are chronic, relapsing inflammatory disorders of the gastrointestinal tract.

LRRK2 is a kinase encoded by a gene that contains a non-coding polymorphism (SNP). LRRK2 has been associated with and is a risk factor for inflammatory bowel disease. NIH

inventors have shown that human cells expressing this SNP have increased levels of LRRK2 and, correspondingly, mice with increased levels of LRRK2 exhibit more severe Dextran Sulfate colitis. In various studies of the role of LRRK2 in cell signaling, NIH inventors have shown that increased levels of LRRK2 lead to increased pro-inflammatory cytokine secretion. Also, an inhibitor of LRRK2 is shown to abrogate the pro-inflammatory activity of LRRK2 both *in vitro* and *in vivo*.

Potential Commercial Applications: Treatment for or prevention of Intestinal Bowel Disorders.

Competitive Advantages

- A LRRK2 inhibitor would be a unique form of anti-inflammatory therapy that will complement or compete with an array of cytokines in primary treatment for IBD.
- A LRRK2 inhibitor would provide a much needed alternate mode of therapy.

Development Stage

- Early-stage
 - In vitro data available
 - In vivo data available (animal)
- Inventors:* Warren Strober, Ivan J. Fuss, Tetsuya Takagawa, Atsushi Kitani (all of NIAID).

Intellectual Property: HHS Reference No. E-070-2014/0—US Provisional Application No. 61/993,637 filed May 15, 2014.

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

Dated: January 22, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015-01610 Filed 1-28-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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

The meetings 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning