

*Contact Person:* Weihua Luo, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435-1170, [luow@csr.nih.gov](mailto:luow@csr.nih.gov).

*Name of Committee:* Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics C Study Section.

*Date:* June 23-24, 2011.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Michael M. Sveda, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, 301-435-3565, [svedam@csr.nih.gov](mailto:svedam@csr.nih.gov).

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review Group, Gene and Drug Delivery Systems Study Section.

*Date:* June 23-24, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

*Contact Person:* Amy L. Rubinstein, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892, 301-408-9754, [rubinsteinal@csr.nih.gov](mailto:rubinsteinal@csr.nih.gov).

*Name of Committee:* Population Sciences and Epidemiology Integrated Review Group, Social Sciences and Population Studies Study Section.

*Date:* June 23, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Loews Annapolis Hotel, 126 West Street, Annapolis, MD 21401.

*Contact Person:* Bob Weller, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3160, MSC 7770, Bethesda, MD 20892, (301) 435-0694, [weller@csr.nih.gov](mailto:weller@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, *Small Business:* Risk Prevention and Health Behavior.

*Date:* June 23-24, 2011.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* West Chicago Lakeshore, 644 North Lake Shore Drive, Chicago, IL 60611.

*Contact Person:* Claire E. Gutkin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3106, MSC 7808, Bethesda, MD 20892, 301-594-3139, [gutkincl@csr.nih.gov](mailto:gutkincl@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, *Member Conflict:* Environmental Causes for Retinopathy.

*Date:* June 23-24, 2011.

*Time:* 11 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Raya Mandler, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217, MSC 7840, Bethesda, MD 20892, 301-402-8228, [rayam@csr.nih.gov](mailto:rayam@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Cancer Etiology Overflow.

*Date:* June 24, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Elaine Sierra-Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301-435-1779, [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, *RFA Panel:* Understanding and Promoting Health Literacy.

*Date:* June 24, 2011.

*Time:* 8 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Crowne Plaza Hotel—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

*Contact Person:* Rebecca Henry, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, 301-435-1717, [henryrr@mail.nih.gov](mailto:henryrr@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 5, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-11661 Filed 5-11-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences; Notice of Closed Meeting

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 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 the 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 Institute of Environmental Health Sciences Special Emphasis Panel; Mitochondrial Biomarkers Review Meeting.

*Date:* June 2, 2011.

*Time:* 3 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Garden Inn Durham Southpoint, 7007 Fayetteville Road, Durham, NC 27713.

*Contact Person:* Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P. O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307, [bass@niehs.nih.gov](mailto:bass@niehs.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: May 5, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-11662 Filed 5-11-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of Biotechnology Activities; Recombinant DNA Research: Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

**AGENCY:** National Institutes of Health (NIH), PHS, DHHS.

**ACTION:** Notice of final actions under the *NIH Guidelines* and notice of an addition to Appendix D of the *NIH Guidelines*.

**SUMMARY:** A proposal to certify *Kluyveromyces lactis* as a host-vector 1 system has been reviewed by the NIH

Recombinant DNA Advisory Committee (RAC) and approved by the NIH Director. This decision is based upon the determination that the *K. lactis* host-vector 1 system affords a moderate degree of biological containment equal to other certified host-vector 1 systems presently listed in the *NIH Guidelines*.

Moreover, it has been determined that certain research with this host-vector system does not present a significant risk to health and the environment and therefore will be exempt from the *NIH Guidelines* (See Section III-F-6 and Appendix C). Appendix C has been modified to indicate the nature of the research that is exempt when performed in a *K. lactis* certified host-vector 1 system.

In addition, the Office of Biotechnology Activities is updating Appendix D of the *NIH Guidelines* to include additional lines of experimentation approved by the NIH Director; in this case an experiment involving the introduction of tetracycline resistance into *Chlamydia trachomatis* that falls under Section III-A-1-a of the *NIH Guidelines*.

**DATES:** The final action regarding certification of a new host-vector 1 system is effective April 14, 2011.

**FOR FURTHER INFORMATION CONTACT:** Background documentation and additional information can be obtained from the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892; e-mail at [oba@od.nih.gov](mailto:oba@od.nih.gov), or telephone at 301-496-9838. The NIH OBA Web site is located at: <http://oba.od.nih.gov/oba/>.

**SUPPLEMENTARY INFORMATION:** Under the *NIH Guidelines*, certification of a host-vector 1 system is based on assessment of the biological containment provided by the recombinant DNA vector (plasmid or virus) and the host (bacterial or lower eukaryote) in which the vector is propagated in the laboratory. Per the *NIH Guidelines*, a combination of vector and host can be certified based on the ability of this system to provide biological containment so that "the following types of 'escape' are minimized: (i) Survival of the vector in its host outside of the laboratory and (ii) transmission of the vector from the propagation host to other non-laboratory hosts" (see Appendix I-I). Host-vector 1 systems provide a moderate level of containment (Appendix I). Most low volume (< 10 liters) research with host-vector 1 systems is exempt from the *NIH Guidelines* and therefore does not require registration with the IBC. High volume (> than 10 liters) research with

a certified host-vector 1 system requires IBC review; however, the required containment practices are not as comprehensive as those required for similar research not involving a host-vector 1 system. For example, because of the biological containment provided by the host-vector 1 system, large volume research in a host-vector 1 system does not require all recombinant material to be handled in a closed system.

In making a determination regarding whether a host-vector combination provides moderate biological containment and therefore can appropriately be certified as a host-vector 1 system, the following information is considered: the host's natural habitat and growth requirements; its physiologic properties, particularly reproduction, survival, and mechanisms for exchange of genetic information; and the history of the particular strains and vectors to be used, including mutations that render this organism less able to survive or transmit genetic information.

The Office of Biotechnology Activities received a request from New England BioLabs (NEB) to certify *K. lactis* as a host-vector 1 system under the *NIH Guidelines* and to exempt certain research with this host-vector system. Specifically, NEB requested certification of two parental, laboratory-adapted lineages of *K. lactis*. One is a strain selected by the *K. lactis* research community for genome sequencing and the second is a *K. lactis* strain originally isolated in the 1980s from a dairy process. This latter strain has been used as a host strain in the food industry for heterologous protein expression. In addition, NEB has created host strains that are genetically modified through deletion of one or more genes, including genes involved in the synthesis of cellular components (e.g., those involved in biosynthetic activities and modification of host proteins: proteases and glycosylases). Most of the vectors proposed by NEB are plasmids derived from pGBN1, a *K. lactis*-*Escherichia coli* shuttle plasmid containing selectable markers for growth in both organisms. The pGBN1-derived plasmids stably integrate into the *LAC4* region of the *K. lactis* chromosome. Other available plasmids for use in *K. lactis* are derived from the *Saccharomyces cerevisiae* 2-micron plasmid and remain stable in an episomal state with a copy number of about 50.

NEB noted that *K. lactis* has a 20+ year history of safe use as an expression system in regulated food industry processes. NEB further stated that they had found *K. lactis* to provide an

excellent system for heterologous protein expression. With regards to its appropriateness for certification as a host-vector 1 system, *K. lactis* is closely related to *S. cerevisiae*, which is certified as a host-vector 1 system. *K. lactis*, however, is unable to exchange genetic material with this closely related yeast. *K. lactis* can exchange genetic material only with itself and in rare cases with other *Kluyveromyces* species, thus affording an additional degree of biological containment.

On November 15, 2010, background information on these actions and instructions for submitting public comment were published in the **Federal Register** (75 FR 69687). No public comments were received regarding the proposal to certify *K. lactis* as a host-vector 1 system. On December 7, 2010, the RAC discussed whether there are sufficient data as outlined in Appendix I-II-B-1 of the *NIH Guidelines* to certify *K. lactis* and its associated plasmids as a host-vector 1 system.

In its assessment of the request, the RAC considered a number of factors, including that: (1) *K. lactis* is a natural and indispensable component of cultured dairy processes (including yogurt, cheese and buttermilk) and has been used widely in the food industry to express heterologous proteins (e.g. lactase which has been used to treat lactose intolerance); (2) its optimum growth is at 30 °C, thereby limiting its survival within humans and most other warm-blooded animals; (3) genetic exchange is limited to a few *Kluyveromyces* species, which rarely cause any disease in humans (with the exception of rare reports of superficial skin disease with *K. marxianus*, a closely related yeast), and (4) there are no documented cases of disease or toxicity attributed to *K. lactis*. With regard to the plasmids proposed for certification, the Committee noted that plasmids that can replicate in *K. lactis* exist in low copy number, will not be efficiently transferred between *K. lactis* strains, and are not transferrable to other yeast via mating (*K. lactis* is unable to mate with other yeast). In sum, it was determined that *K. lactis* meets the requirements of a host-vector 1 system.

The RAC recommended that laboratory-adapted strains of *K. lactis* should be certified as a host-vector 1 system, as it was the Committee's assessment that laboratory adapted strains grown under optimized laboratory conditions will be at a selective disadvantage, and thus less competitive compared to strains isolated from the wild. Of note, even wild-type *K. lactis* has a limited natural habitat and growth requirement, mainly

restricted to lactose-rich environments. Plasmids that can be used in *K. lactis* are not capable of replicating to high copy numbers. Due to the additional containment and corresponding vastly reduced risk to either human health or the environment afforded by host-vector 1 systems, research with this system will be exempt from the *NIH Guidelines* unless the system is: (i) Capable of producing a molecule that is toxic to vertebrates; (ii) contains DNA from a Risk Group 3 or 4 organism (see Appendix B of the *NIH Guidelines*); or (iii) will be employed for large scale (> 10 liters) experimentation.

The following new appendix (C-IV) will be added to Appendix C of the *NIH Guidelines*. The current Appendices C-IV through C-VIII (and sub-appendices) will be renumbered to Appendices C-V through C-IX, respectively.

#### **Appendix C-IV *Kluyveromyces* Host-Vector Systems**

Experiments involving *Kluyveromyces lactis* host-vector systems, with the exception of experiments listed in Appendix C-IV-A, are exempt from the *NIH Guidelines* provided laboratory-adapted strains are used (*i.e.* strains that have been adapted to growth under optimal or defined laboratory conditions). For these exempt experiments, BL1 physical containment is recommended. For large-scale fermentation experiments, the appropriate physical containment conditions need be no greater than those for the host organism unmodified by recombinant DNA techniques; the Institutional Biosafety Committee may specify higher containment if deemed necessary.

#### **Appendix C-IV-A Exceptions**

The following categories are not exempt from the *NIH Guidelines*: (i) Experiments described in Section III-B, which require NIH/OBA and Institutional Biosafety Committee approval before initiation; (ii) experiments involving DNA from Risk Groups 3, 4, or restricted organisms (see Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard*, and Sections V-G and V-L, *Footnotes and References of Sections I through IV*) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III-D-2 with prior Institutional Biosafety Committee review and approval; (iii) large-scale experiments (*e.g.*, more than 10 liters of culture), and (v) experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F,

*Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*).

#### **Additions to Appendix D of the NIH Guidelines**

In accordance with Section III-A of the *NIH Guidelines*, Appendix D of the *NIH Guidelines* will be modified as follows to reflect a recent approval for the transfer of a drug resistance trait to a microorganism.

Appendix D-118. Dr. Harlan Caldwell at the Rocky Mountain Laboratories may conduct experiments to deliberately introduce a gene encoding tetracycline resistance into *Chlamydia trachomatis* serovar L2. This approval is specific to Dr. Caldwell and research with this resistant organism may only occur under the conditions as specified by the NIH Director. This approval was effective as of April 26, 2010.

Dated: May 6, 2011.

**Jacqueline Corrigan-Curay,**

*Acting Director, Office of Biotechnology Activities, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HOMELAND SECURITY**

### **Transportation Security Administration**

[Docket No. TSA-2001-11120]

#### **Intent To Request Renewal From OMB of One Current Public Collection of Information; Imposition and Collection of Passenger Civil Aviation Security Service Fees**

**AGENCY:** Transportation Security Administration, DHS.

**ACTION:** 60-day Notice.

**SUMMARY:** The Transportation Security Administration (TSA) invites public comment on one currently approved Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652-0001, abstracted below that we will submit to OMB for renewal in compliance with the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. The collection involves air carriers maintaining an accounting system to account for the passenger civil aviation security service fees collected and reporting this information to TSA on a quarterly basis, as well as retaining the data used for these reports for a six-year rolling period.

**DATES:** Send your comments by July 11, 2011.

**ADDRESSES:** Comments may be e-mailed to [TSAPRA@dhs.gov](mailto:TSAPRA@dhs.gov) or delivered to the TSA PRA Officer, Office of Information Technology (OIT), TSA-11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6011.

**FOR FURTHER INFORMATION CONTACT:** Joanna Johnson at the above address, or by telephone (571) 227-3651.

#### **SUPPLEMENTARY INFORMATION:**

##### **Comments Invited**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at <http://www.reginfo.gov>. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

##### **Information Collection Requirement**

*OMB Control Number 1652-0001; Imposition and Collection of Passenger Civil Aviation Security Service Fees.* In accordance with the Aviation Transportation Security Act (ATSA) (49 U.S.C. 44940) and relevant TSA Regulations (49 CFR part 1510), TSA imposes a Passenger Civil Aviation Security Service Fee (September 11th Security Fee) on passengers of both foreign and domestic air carriers ("air carriers") on flights originating at airports in the United States to assist with aviation security costs.

The September 11th Security Fee is used to help defray the costs of providing Federal civil aviation security services. This information collection requires air carriers to submit to TSA the amount of September 11th Security Fees they have imposed, collected, remitted, and refunded. The retention of this data is necessary for TSA to impose, collect, and regulate the Security Fee.