

Dated: July 6, 2001.

Elizabeth M. Duke,

Acting Administrator.

[FR Doc. 01-17409 Filed 7-10-01; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Validation of Questionnaires Used for Occupational Exposure Assessment in Case-Control Studies: Occupational History Questionnaire With Foundry Worker and Textile Industry Job Modules

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 11, 2001, page 2433, Volume 66, No. 8, and allowed 60 days for public comment. No public comments were received. NCI fulfilled only one request for a copy of the study protocol and questionnaire.

The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, and information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Validation of Questionnaires Used for Occupational Exposure Assessment in Case-Control Studies: Occupational History Questionnaire with Foundry Worker and Textile Industry Job Modules. **Type of Information Collection Request:** New. **Need and Use of Information Collection:** This study will investigate the validity and reliability of exposure assessments based on occupational history questionnaires supplemented with industry specific job modules as compared to exposure assessments made based on actual measurement taken in the workplace environments. The results will be used to assess the potential magnitude of exposure misclassification in case-control studies using these types of exposure assessment methods. **Frequency of Response:** One time study. **Affected Public:** Large and small factories in Shanghai, China. **Type of Respondents:**

Factory workers. The annual burden is as follows: *Estimated Number of Respondents:* 120; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Respondent:* 0.5 hours; and *Estimated Total Annual Burden Hours Requested:* 60. There are no annualized costs to respondents. There are no Capital Costs to report and 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 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.

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, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Joseph Coble, Project Officer, National Cancer Institute, 6120 Executive Blvd, EPS 8110, Rockville, MD, 20892-7240, or call non-toll-free number (301) 435-4702, email your request to jcoble@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received on or before August 10, 2001.

Dated: July 2, 2001.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 01-17281 Filed 7-10-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: Natural Killer Cells in Xenotransplantation and Establishment of a Target Cell Line Producing Porcine Endogenous Retrovirus

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The invention described below is owned by an agency of the U.S. Government and is 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.

ADDRESSES: Licensing information for the technology described below may be obtained by contacting John Rambosek, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7056 ext. 270; fax: 301/402-0220; e-mail: rambosej@od.nih.gov.

SUPPLEMENTARY INFORMATION: The worldwide shortage of human organs and tissues for allotransplantation combined with recent advances in transplantation immunobiology, surgery and medicine, have sparked renewed interest in the clinical use of xenotransplantation, the use of living nonhuman animal materials for the treatment of human diseases. In addition to whole organ transplants, cellular implants and ex vivo use of living material from animal sources have been suggested for treatment of disease in human patients. For a variety of reasons, the pig is currently the source animal of choice for xenotransplantation in humans, but there are two major obstacles to successful pig to human xenotransplantation. These are the immune response, responsible for rejecting xenotransplants, and the risk of transmission of infection including porcine endogenous retrovirus, which, at least at the present time, cannot be removed from the xenotransplantation porcine source. Natural killer (NK) cells play an important role in the delayed rejection of xenotransplants, and have been shown to infiltrate rejecting grafts.

Current efforts in the Laboratory of Immunology and Virology, Division of Cellular and Gene Therapies, Center for Biologics Evaluation and Research,

FDA, are aimed at understanding the human NK cell response to porcine target cells. Findings suggest that NK cells have the capacity to participate in early stages (hyperacute or acute rejection) of xenograft rejection as well as later stages (delayed rejection). In addition, human NK cell activity against porcine cells as measured by lysis and proliferation, is regulated by certain cytokines such as interleukin (IL)-2, IL-12, and IL-15, but not by IL-18 and IL-8. Moreover, the human NK cell response to porcine endothelial cells is regulated by the combination of redox status and nitric oxide (NO) availability, such that under conditions of oxidative stress, lysis of porcine endothelial cells is inhibited by NO through a nuclear factor-kappa B-dependent pathway. Finally, in the process of carrying out these investigations, a new porcine cell line, MS-PBMC-J2 (J2), was established from the peripheral blood of a NIH miniswine. J2 constitutively produces infectious porcine endogenous retrovirus. J2 expresses porcine CD2, CD8, CD16, CD31, and MHC class I and class II but does not express CD3 or CD4. Phenotypically it resembles NK cells, but does not mediate NK-like activity. Further studies into the regulation of human NK cell anti-porcine cytotoxicity are underway, and other experiments using J2 as a model of PERV production are planned.

The cell line (our reference no. E-046-01/0) is available for licensing under a Biological Materials License Agreement. The scientists may also be interested in collaborative arrangements for the further research and development of this technology.

Dated: June 29, 2001.

Jack Spiegel,

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

[FR Doc. 01-17289 Filed 7-10-01; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 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 Cancer Institute Initial Review Group Subcommittee E—Cancer Epidemiology, Prevention & Control.

Date: July 31–August 1, 2001.

Time: 7 am to 2 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Avenue, NW, Washington, DC 20007.

Contact Person: Mary C. Fletcher, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, RM 8115, Bethesda, MD 20852, 301/496-7413.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 29, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-17284 Filed 7-10-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 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 Cancer Institute Initial Review Group Subcommittee D—Clinical Studies.

Date: July 31–August 1, 2001.

Time: 7 pm to 6 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Avenue, N.W., Washington, DC 20007.

Contact Person: William D. Merritt, PhD, Scientific Review Administrator, Grants Review Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, room 8129, MSC 8328, Bethesda, MD 20892-8328, 301-496-9767.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 29, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-17285 Filed 7-10-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 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 Cancer Institute Initial Review Group Subcommittee C—Basic & Preclinical.

Date: July 31–August 2, 2001.

Time: 4 pm to 12 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Michael B. Small, PhD, Scientific Review Administrator, Grants