DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 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: 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, the National Cancer Institute (NCI) 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: 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.

Estimated Total Annual Burden Hours Requested: 60.

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 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.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before March 12, 2001.

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 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.*

Dated: January 3, 2001.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 01–801 Filed 1–10–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Identification and Development of Chemical Compounds That Interact With the Polo-Box of Polo Kinases, as Potential Therapeutic Targets for the Inhibition of Cellular Proliferation

National Cancer Institute (NCI) has extended the deadline for submission of written notices and proposals regarding the CRADA opportunity described in the **Federal Register** Notice number 213, volume 65, dated November 2, 2000.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of extension of announcement of opportunity for a Cooperative Research and Development Agreement (CRADA) for the identification and development of chemical compounds that interact with the polo-box of polo kinases, as potential therapeutic targets for the inhibition of cellular proliferation.

SUMMARY: Members of the polo subfamily of protein kinases play important roles in cell proliferation, and regulation of polo kinases may be crucial in the control of cell division. The polo kinases contain a distinct region of homology in the C-terminal non-catalytic domain, termed the polo-box. Scientists from the National Cancer Institute (NCI) have demonstrated that over-expression of this non-catalytic C-terminal domain in budding yeast results in a dominant-negative inhibition of cell division. NCI seeks a Cooperative Research and Development Agreement (CRADA) Collaborator to aid in the identification and development of chemical compounds that interact with the polo-box of polo kinases, as potential therapeutic targets for the inhibition of cellular proliferation.

DATES: Interested parties should notify this office in writing of their interest in filing a formal proposal on or before March 12, 2001. Potential CRADA Collaborators will then have until on or before April 11, 2001 to submit a formal proposal. CRADA proposals submitted thereafter may be considered if a suitable CRADA Collaborator has not been selected.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Laura A. Henmueller, Ph.D., Technology Development Specialist (Tel: 301–496–0477, FAX: 301–402–2117), Technology Development and Commercialization Branch, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852. Inquiries directed to obtaining patent license(s) needed for participation in the CRADA opportunity should be addressed to Vasant Gandhi, J.D., Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, (Tel: 301–496–7056, ext. 224, FAX: 301–402–0220).

SUPPLEMENTARY INFORMATION: A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into with NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987 as amended. NCI is looking for a CRADA partner to aide NCI in the identification and development of chemical compounds which act as polo-box inhibitors. The expected duration of the

CRADA would be from one (1) to five (5) years.

Members of the polo subfamily of protein kinases appear to play pivotal roles in cell division and proliferation. These include mammalian Plk, Snk, and Fnk/Prk, *Xenopus laevis* Plx1, *Drosophila melanogaster* polo, *Schizosaccharomyces pombe* Plo1, and *Saccharomyces cerevisiae* Cdc5. The polo subfamily members are characterized by the presence of a distinct region of homology in the C-terminal non-catalytic domain, termed the polo-box, which is essential for subcellular localization and mitotic functions of the polo kinases. Regulation of polo kinases may be crucial in the control of cell division. In mammalian cells, Plk is expressed at high levels in mitotically active cells and in tumors of various origins. Constitutive expression of Plk in NIH3T3 cells induces oncogenic focus formation, and these Plk-transformed cells can form tumors in nude mice. These data suggest that Plk expression is closely related to cellular proliferation, and that uncontrolled Plk expression may lead to the development of cancers in humans. Genetic and biochemical analyses indicate that polo kinases regulate diverse cellular events at various stages of the M phase. In addition to their roles in spindle formation and centrosome maturation, polo kinases appear to regulate important biochemical steps at the G2/M transition, such as activation of Cdc2 through Cdc25C phosphatase, DNA damage checkpoint adaptation, and activation of the anaphase-promoting complex (APC) in various eukaryotic systems. In addition, recent data suggest that polo kinases play important roles in cytokinesis.

In budding yeast, overexpression of the non-catalytic C-terminal domain of either Plk or Cdc5 (plkΔN or cdc5ΔN), but not the corresponding polo-box mutant, results in severe connected cell morphology. Provision of functional Cdc5 remedies this phenotype, indicating that over-expression of *cdc*5Δ*N* or *plk*Δ*N* results in a dominant-negative inhibition of cell division and that an intact polo-box is required for this event. These data raise an intriguing possibility that conditional expression of the polo-box domain may selectively inhibit the mitotic functions of polo kinases. Furthermore, our observation suggests that the polo-box peptide may act as a potential anti-cancer therapeutic agent. Alternatively, isolation of small chemical compounds that bind to the polo-box and interfere with its function may yield a strategy to regulate highly proliferative malignant cells. We have developed two yeast strains that conditionally express the polo-box domains of Plk (KLY1212) or Cdc5 (KLY1083). Isolation of chemical compounds alleviating the dominant-negative cell division defect of these strains may lead to identification of polo-box inhibitors. Since the polo-box is an essential and unique domain for polo kinases, these inhibitors may likely provide selective tools to control the cell proliferation without interfering with other protein kinases.

The described methods are the subject of a U.S. provisional patent application filed May 23, 2000 by the Public Health Service on behalf of the Federal Government. Furthermore, the initial report and characterization of the invention is described in: Song S, and Lee KS. A novel function of *Saccharomyces cerevisiae* CDC5 in cytokinesis (submitted for publication). Further reference to the invention can be found in: (1) Song S, Grenfell TZ, Garfield S, Erikson RL, and Lee KS. (2000). Essential function of the polo box of Cdc5 in subcellular localization and induction of cytokinetic structures. Mol. Cell. Biol. 20, 286–298, and (2) Lee KS, Grenfell TZ Yarm, FR, and Erikson RL (1998). Mutation of the polo-box disrupts localization and mitotic functions of the mammalian polo kinase Plk. Proc. Natl. Acad. Sci. USA 95:9301–9306.

Under the present proposal, the goal of the CRADA will involve the following:

(1) Identification and isolation of chemical compounds that alleviate the dominant-negative cell division defect of yeast strains that conditionally express the polo-box domains of Plk or Cdc5.

(2) Development of these chemical compounds as tools to control cellular proliferation without interfering with other protein kinases.

Party Contributions

The role of the NCI in the CRADA may include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.

2. Providing the CRADA Collaborator with information and data relating to polo kinases.

3. Planning research studies and interpreting research results.

4. Carrying out research which validates and expands on the role of the dominant-negative inhibition of cell proliferation found using the intact polo-box.

5. Publishing research results.

6. Developing additional potential applications related to inhibition of cell proliferation using polo-box inhibitors.

The Role of the CRADA Collaborator May Include, but Not Be Limited To:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.

2. Planning research studies and interpreting research results.

3. Providing technical and/or financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.

4. Publishing research results.

Selection Criteria for choosing the CRADA collaborator may include, but not be Limited to:

1. A demonstrated record of success in the areas of isolation, purification, characterization, and therapeutic development of chemical compounds.

2. A demonstrated background and expertise in cancer-related sciences.

3. The ability to collaborate with NCI on further research and development of this technology. This ability will be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.

4. The demonstration of adequate resources to perform the research and development of this technology (*e.g.* facilities, personnel and expertise) and to accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

5. The willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.

6. The demonstration of expertise in the commercial development and production of products related to this area of technology.

7. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

8. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

9. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

10. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the distribution of future patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license

for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: December 19, 2000.

Kathleen Sybert,

Chief, Technology Development and Commercialization Branch, National Cancer Institute, National Institutes of Health.

[FR Doc. 01–813 Filed 1–10–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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: Training Grant and Career Development Review Committee.

Date: February 1–2, 2001.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, N.W., Washington, DC 20037.

Contact Person: Raul A. Saavedra, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–9223.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: January 4, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–802 Filed 1–10–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel.

Date: January 9, 2001.

Time: 2:00 pm to 4:00 pm.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Raul A. Saavedra, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–9223.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: January 4, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–803 Filed 1–10–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of 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 a meeting of the National Advisory Council on Drug Abuse.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Council on Drug Abuse.

Date: February 13–14, 2001.

Closed: February 13, 2001, 1 pm to 5:30 pm.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Open: February 14, 2001, 9 am to 4:30 pm.

Agenda: This portion of the meeting will be open to the public for announcements and reports of administrative, legislative and program developments in the drug abuse field.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Contact Person: Teresa Levitin, PhD, Director, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, Bethesda, MD 20892–9547, (301) 443–2755.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)