

1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: A Prospective Study of Diet and Cancer in Members of the American Association of Retired Persons (AARP). **Type of Information Collection Request:** Reinstatement with change, OMB No. 0925-0423, which expired on 09/30/98. **Need and Use of Information Collection:** This study is to examine prospectively the relation between diet and major cancers (especially those of the breast, large bowel, and prostate) in population of early- to late-middle aged men and women in the United States. In order to minimize two problems that historically have plagued observational epidemiologic studies of diet and cancer—dietary measurement error and dietary homogeneity—this study is large and oversampled screenees within extreme categories of dietary intake. Understanding the relationship between diet and cancers of the breast, large bowel, and prostate has critical implications for the American people. This uniquely designed study has a capacity greater than that of any previous study for demonstrating these important connections between dietary factors and major cancers. **Frequency of Response:** One-time study. **Affected Public:** Individuals or households and business or other for-profit. **Type of Respondents:** Male and Female AARP members aged 50–69 years. The total annual reporting burden is as follows: **Estimated Number of Respondents:** 150,166; **Estimated Number of Responses per Respondent:** 1; **Average Burden Hours per Response:** 0.25; and **Estimated Total Annual Burden Hours Requested:** 37,542. There are no Capital Costs, Operating Costs, and/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 function 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 the 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 20530, 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: Arthur Schatzkin, M.D., Dr.P.H., Nutritional Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Executive Plaza South, Suite 7040, Rockville, Maryland 28092, or call non-toll free (301) 594-2931, or E-mail your request, including your address to schatzka@mail.nih.gov

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before September 24, 2001.

Dated: August 15, 2001.

Reesa Nichols,
NCI Project Clearance Liaison.

[FR Doc. 01-21264 Filed 8-22-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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.

Single-Chain Antibody Fragment Protein Binding to HIV-1 Integrase

Eugene Barsov and Stephen Hughes (NCI), DHHS Reference No. E-193-01/0

Licensing Contact: Sally Hu; 301/496-7056 ext. 265; e-mail: hus@od.nih.gov

Integration of the viral DNA into the host genome is a prerequisite for efficient viral transcription and establishment of productive HIV-1 infection in humans. This function is mediated by the viral protein integrase. The invention discloses a single-chain Fab fragment of a murine monoclonal antibody (scFv35) that is able to inhibit the viral integrase. The antibody fragment can be recombinantly expressed. The Fab fragment is further described in the Journal of Virology 70 (7), pp 4484-4495, 1996. It is available for licensing through a Biological Materials License Agreement as no patent application has been filed.

Plasmid Based Assay for the in vitro Repair of Oxidatively Induced DNA Double Strand Breaks

Thomas A. Winters, Elzbeitz Pastwa, and Ronald D. Neumann (CC), DHHS Reference No. E-319-00/0 filed 06 Oct 2000

Licensing Contact: Wendy Sanhai; 301/496-7736 ext. 244; e-mail: sanhaiw@od.nih.gov

We describe a new non-radioactive, high throughput in vitro assay for the repair of oxidatively induced DNA double-strand breaks by HeLa cell nuclear extracts. The assay measures non-homologous end joining (NHEJ) repair by employing linear plasmid DNA containing DNA double-strand breaks (DSBs) produced by either the radiomimetic drug bleomycin or StuI restriction endonuclease. The complex structure of the bleomycin-induced DSB more closely models naturally occurring DSBs than restriction enzyme induced DSBs. Although initial optimization reactions were conducted with these DNA molecules, any double-strand-break-inducing agent may be employed to create the linear DNA substrates used in the assay.

Cellular extraction and initial end-joining reaction conditions were optimized with restriction enzyme cleaved DNA to maximize ligation activity. Several parameters affecting ligation were examined including

extract protein concentration, substrate concentration, ATP utilization, reaction time, temperature, and effect of ionic strength. Similar reactions were performed with the bleomycin-linearized substrate. In all cases, end-joined molecules ranging from dimers to higher molecular weight forms were produced and observed directly in agarose gels stained with Vistra Green and imaged with a FluorImager 595. This method permits detection of less than or equal to 0.25 ng double-stranded DNA per band directly in post-electrophoretically stained agarose gels. Therefore, the optimized end joining reactions required only 100 ng or less of substrate DNA, and up to 50% conversion of substrate to product was achieved.

The DSB end structure was shown to directly affect repair of the strand break. Bleomycin-induced DSBs were repaired at a 6-fold lower rate than blunt-ended DNA, and initiation of the reaction lagged behind that of the blunt-end rejoining reaction. Recent experiments have shown repair of DSBs produced by γ -rays to be 15-fold less efficient than for DSBs produced by restriction enzyme. While repair of the high-LET-like DSB produced by 125I was near the lower limit of detection. Thus, as the cytotoxicity of the DNA damaging agent increases, the DSB created by the agent is less efficiently repaired.

Repair efficiency is also dependent upon the repair capacity of the cellular extract employed as a source of repair enzymes. These repair activities are known to vary from tissue to tissue, and person to person.

Therefore, by using patient samples as a source of enzyme activities, our method might be employed clinically as a predictive assay for patient sensitivity to DNA damaging agents. Knowledge of a patient's sensitivity to DNA damaging agents may permit more effective choices to be made when selecting treatment options in cases of cancer, and other diseases where DNA damaging agents are commonly used.

Sensitization of Cancer Cells to Immunoconjugate-Induced Cell Death by Transfection With Interleukin-13 Receptor Alpha-Chain

R. Puri (FDA), DHHS Reference No. E-032-00/1 filed 31 August 2000

Licensing Contact: Richard Rodriguez; 301/496-7056 ext. 287; e-mail: rodrigur@od.nih.gov

The claimed technology relates to the use of gene transfer techniques to sensitize cancer cells to IL-13 Receptor-mediated immunotoxin induced cell death. Specifically, the inventor has shown that stable gene transfer of the

IL-13R α 2 chain, of the IL-13 receptor, significantly sensitizes cancer cells to the effects of IL-13 toxin by approximately 520-1000-fold. Since many cancers, e.g., brain, breast, lung, head and neck, pancreatic, prostate or liver, can be inoperable, direct intratumoral administration of treatment-agents may become necessary. As such, the claimed invention shows that a combination approach, utilizing both gene transfer and systemic or locoregional cytotoxin therapy, may be available as a new potent treatment regimen for intractable or refractory cancers.

Dated: August 13, 2001.

Jack Spiegel,

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

[FR Doc. 01-21265 Filed 8-22-01; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Research Resources Council, September 13, 2001, 9:15 AM to September 13, 2001, 5:00 PM, National Center for Research Resources, National Institutes of Health, Conference Room 10, Building 31, Bethesda, MD, 20892 which was published in the **Federal Register** on August 13, 2001, 66 FR 42549.

Executive Subcommittee Meeting scheduled for September 13, 2001 at 8:00 a.m.-9:00 a.m. has been cancelled. The meeting is partially Closed to the public.

Dated: August 16, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-21254 Filed 8-22-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 section 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 Child Health and Human Development Special Emphasis Panel.

Date: August 29, 2001.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: 6100 Executive Blvd., Room 5E01, Rockville, Md 20852 (Telephone Conference Call).

Contact Person: Robert H. Stretch, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5E01, MSC 7510, Bethesda, MD 20892, (301) 435-6912.

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. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: August 16, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-21252 Filed 8-22-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Arthritis and Musculoskeletal and Skin Diseases; 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 Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

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