the importance of minimizing costs for repetitive, return visits to obtain respondent cooperation, NIDA is considering the provision of a reasonable cost incentive to reimburse respondents for their time.

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.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Susan David, Project Officer; Division of Epidemiology and Prevention Research, National Institutes on Drug Abuse, Room 9A54, 5600 Fishers Lane, Rockville, MD 20857; or call non-toll-free number (301) 443–6543; or fax to (301) 443–2636; or e-mail your request, including your address, to: Sd69t@nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received by January 29, 1999.

Dated: November 19, 1998.

Laura Rosenthal,

Executive Officer, NIDA.

[FR Doc. 98–31728 Filed 11–27–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; Survey of Colorectal Cancer Screening Practices in Health Care Organizations

SUMMARY: In compliance with the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comments on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget for review and approval.

PROPOSED COLLECTION: *Title:* Survey of Colorectal Cancer Screening Practices in Health Care Organizations. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will measure primary care and specialty physicians' knowledge, attitudes, and practice patterns related to colorectal cancer screening and diagnostic follow-up. This study also will assess guidelines, policies, and programs to provide or promote colorectal cancer screening within health plans. The purpose of this study is to obtain current, nationally representative data on the physician and health system factors that may influence the use of colorectal cancer screening and diagnostic follow-up for suspected colorectal cancer in community practice. Three questionnaires will be administered by mail, telephone, facsmile, or Internet using national samples of physicians and health plans. Study participants will select their preferred response mode. Study participants will be primary care and speciality physicians with active licenses to practice medicine in the U.S., and the medical directors of health plans listed by the American Association of Health Plans. Burden estimates are as follows:

Questionnaire	Estimated # respondents	# responses per respondent	Average burden hours per response	Estimated total annual burden hours
Primare care physician	1,810	1	0.250	452
Speciality physician	1,544	1	0.333	514
Health plan	453	1	0.333	*151*
Total:				1,117

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (a) whether the proposed collection of information is necessary for the performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Send comments to Carrie N. Klabunde, Ph.D., Epidemiologist, National Cancer Institute, EPN 313, 6130 Executive Boulevard, MSC 7344, Bethesda, Maryland 20892–7344, telephone 301–402–3362.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received by January 29, 1999.

Dated: November 19, 1998.

Reesa Nichols,

OMB Project Clearance Liaison.

[FR Doc. 98–31729 Filed 11–27–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Licensing Opportunity and/or Cooperative Research and Development Agreement (''CRADA'') Opportunity: Drug And Method For The Therapeutic Treatment of Lymphomas And Leukemias

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The NIH is seeking Licensee(s) and/or a Cooperative Research and Development Agreement (''CRADA'') to further develop, evaluate, and commercialize a recombinant immunotoxin, termed RFB4(dsFv)–PE38

or BL22, for use in the therapeutic treatment of lymphomas and leukemias. RFB4(dsFv)–PE38 (BL22) is a disulfide-linked recombinant immunotoxin fused to PE38, a mutant form of Pseudomonas Exotoxin (PE), that binds to CD22—a 135kDa phosphoglycoprotein adhesion molecule present on the surface of B-cells. RFB4 is a mouse monoclonal antibody that recognizes an external epitope on the CD22 cell surface antigen and has no detectable cross-reactivity with any other normal cell types. CD22 is a lineage-restricted B-Cell antigen that belongs to the Ig superfamily and is displayed on chronic B-Lymphocytic Leukemia cells and B-cell Non-Hodgkins Lymphoma cells. To kill CD22-positive cells, the RFB4 antibody was used to make a recombinant immunotoxin. To construct the recombinant PE immunotoxin, the variable portions of the heavy and light chains of RFB4 were cloned and the Fv fragments linked together by a disulfide bond to form a disulfide stabilized (ds) construct. The construct was combined by gene fusion with PE38, a truncated version of PE, to form RFB4(dsFv)–PE38, or BL22.

The inventions are claimed in USPN 4,892,827, entitled: ''Recombinant Pseudomonas Exotoxins: Construction of an Active Immunotoxin with Low Side Effects''; USSN 07/865,722, entitled: ''Recombinant Antibody-Toxin Fusion Protein''; USPN 5,696,237, entitled: ''Recombinant Antibody-Toxin Fusion Protein''; and USSN 08/461,825, entitled: ''Recombinant Antibody-Toxin Fusion Protein''; and are available for either exclusive or non-exclusive licensing for these aforementioned applications only (in accordance with 35 U.S.C. 207 and 37 CFR part 404).

DATES: Respondees interested in licensing the invention(s) will be required to submit an ''Application for License to Public Health Service Inventions'' on or before March 1, 1999.

Interested CRADA collaborators must submit a confidential proposal summary to the National Cancer Institute (''NCI'') on or before March 1, 1999, for consideration. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest. CRADA proposals submitted thereafter may be considered if a suitable CRADA collaborator has not been selected.

ADDRESSES: Questions about licensing opportunities may be addressed to J. R. Dixon, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Telephone: (301)–496–7056 ext. 206; Facsimile: (301)–402–0200; E-Mail ''DixonJ@OD.NIH.GOV''. Information about Patent Applications and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement. Respondees interested in licensing the invention(s) will be required to submit an ''Application for License to Public Health Service Inventions''.

Depending upon the mutual interests of the Licensee(s) and the NCI, a Cooperative Research and Development Agreement (CRADA) to collaborate to improve the properties of the RFB4(dsFv)–PE38 immunotoxin may also be negotiated. Proposals and questions about this CRADA opportunity may be addressed to Dr. Patrick Twomey, Technology Development Specialist, Technology Development & Commercialization Branch, National Cancer Institute, 6120 Executive Plaza South-Room 450, Rockville, Maryland 20852; Telephone: (301)–496–0577; Facsimile: (301)–402–2117; email: twomeyp@OTD.NCI.NIH.GOV. Respondees interested in submitting a CRADA proposal should be aware that it may be necessary to secure a license to the above mentioned patent rights in order to commercialize products arising from a CRADA.

SUPPLEMENTARY INFORMATION: NIH/NCI scientists have done toxicity studies with the RFB4(dsFv)–PE38 immunotoxin in mice and cynomolgus monkeys. The immunotoxin is toxic for CD22 positive cells and exhibits antitumor activity in nude mice bearing human B-cell lymphomas. The IC_{50} of BL22 against four Burkitt's lymphoma cell lines range from 0.25–1.5 ng/ml. The dose in mice producing complete regression of subcutaneous CA46 lymphomas was 275 μg/kg on an alternate daily X 3 schedule (WODX3). The LD_{50} in tumors was approximately 1,303 μg/kg and the maximum tolerated dose was 400 μg/kg/dose. Pilot studies in cynomolgus monkeys showed no dose limiting toxicity at doses up to 2,000 μg/kg QODX3 by i.v. bolus. Peak plasma levels were 2.5, 10, and 55 μg/mL in monkeys treated with 100 μg/kg, 500 μg/kg and 2,000 μg/kg BL22, respectively. BL22 was eliminated nonexponentially from plasma with a half-life of approximately 44 to 66 minutes.

In the United States, Non-Hodgkin's lymphomas have a 1998 expected incidence of 55,400 including 24,900 expected deaths. The incidence of Non-Hodgkin's lymphomas has risen 50% during the last 15 years, including 3–4%/year recently, making it one of the most rapidly increasing malignancies in terms of incidence. Chronic lymphocytic leukemias have a 1998 incidence of 7,300 cases with 4,800 deaths. Thus approximately 50,000 patients per year in the U.S. are diagnosed with CD22+ malignant disease, half of which cannot be effectively treated with known modalities. This makes CD22+ malignancies a major public health problem in the U.S. and an appropriate target for newer targeted approaches. Hence, the development of new therapeutic modalities, such as RFB4(dsFv)–PE38, to treat these malignancies is needed.

A Cooperative Research and Development Agreement or CRADA means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995 to collaborate to improve the properties of the RFB4(dsFv)–PE38 immunotoxin. The expected duration of the CRADA would be from one (1) to five (5) years.

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 collaborator with samples of the subject compounds to create, optimize, test and develop targeted drugs for clinical studies.
3. Planning research studies and interpreting research results.
4. Carrying out research to improve the properties of the RFB4(dsFv)–PE38 which include, but are not restricted to, increased production yield, decreased side effects, increased cytotoxic activity and better tissue penetration.
5. Publishing research results.

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

1. Providing sufficient amounts of BL22 for clinical trials.
2. Conducting Phase 2 and Phase 3 clinical trials.
3. Providing significant intellectual, scientific, and technical expertise or experience to the research project.
4. Planning research studies and interpreting research results.
5. Providing samples of the subject compounds to create, optimize, test and develop targeted drugs for clinical studies.
6. Providing technical and/or financial support to facilitate scientific goals and for further design of

applications of the technology outlined in the agreement.

7. Incorporating the immunotoxin into formulations in order to increase the therapeutic efficacy and decrease immunogenicity.

8. Providing immunotoxin for laboratory and animal studies.

9. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

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

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

3. 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.

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

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

6. The demonstration of expertise pertinent to the development of models to evaluate and improve the efficacy of the RFB4 (dsFv)–PE38 immunotoxin for the treatment of lymphomas and leukemias.

7. The demonstration of expertise in the formulation of drugs.

8. The willingness to cooperate with the NCI 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 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: November 5, 1998.

Jack Spiegel,

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

Dated: November 16, 1998.

Kathleen Sybert,

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

[FR Doc. 98–31733 Filed 11–27–98; 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 contacting Dennis H. Penn, Pharm.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 211; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A Mitochondrial-Specific ATP-Binding Transporter Gene (ABC7) Is An Iron Transporter In An Interhited Ataxia-Anemia Syndrome

MC Dean, R Allikmets, AA Hutchinson (NCI)

DHHS Reference No. E–181–98/0 filed Oct 23, 1998

The gene responsible for the rare genetic disease, X-linked siderblastic anemia and ataxia (XLSA/A) has been identified and linked to a mutation of the ATP-Binding transporter gene (ABC7). Two sequence changes which correspond to amino acid changes at positions 50 and 396 were detected. This gene may prove useful as a diagnostic for XLSA/A carriers or as a means to rule out XLSA/A from other siderblastic anemias. ABC7, an iron transporter, may prove to be a valuable tool for studying the function and regulation of muscle cells and the loss of motor function associated with many diseases with faculty iron metabolism, i.e. neuromuscular disease, cardiac disorders and neurological disorders.

Compsitions And Uses of FIG-alpha Gene

J Dean, L Liang, S soyal (NIDDK)

Serial No. 60/069,037 filed Dec. 12, 1997

This application related to an isolated and purified polynucleotide encoding an isolated and purified polypeptide associated with the expression of zona pellucida genes. The mouse zona pellucida is composed of three glycoproteins, ZP1, ZP2 and ZP3, encoded by single-copy genes whose expression is temporarlly and spatially restricted to oocytes. All three proteins are required for the formation of the extracellular zona matrix and female mice with a single disrupted zona gene lack a zona and are infertile. An E-box (CANNTG), located approximately 200 bp upstream of the transcription start site of the ZP1, ZP2 and ZP3, forms a protein-DNA complex present in oocytes and, to a much lesser extent, in testes. The integrity of this E-box in ZP2 and ZP3 promoters is required for expression of luciferase reporter genes microinjected into growing oocytes. The presence of the ubiquitous transcription factor E12 in the complex was used to identify a novel basic helix-loop-helix protein FIGα (Factor In the Germline alpha) whose expression was limited to oocytes within the ovary.)

This invention relates to the molecular characterization of FIGα, a novel germ cell specific bHLB transcription factor that binds as a heterodimer with E12 to the E-box in the promoter region of all three mouse zona pellucida genes and has the ability to transactivate reporter gene constructs in vitro. FIGα is critical for folliculogenesis and has a role in the coordinate, oocyte-specific expression of the three zona pellucida genes, the products of which for an extracellular matrix required for fertilization and early development. This invention also relates to monoclonal and polyclonal antibodies, which recognize the FIGα polypeptide.