visit our Web site at *http://healthit.hhs.gov* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: May 17, 2010.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2010–12715 Filed 5–26–10; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Assessing the Long-Term Impacts of the John E. Fogarty International Center's Research and Training Programs

ACTION: Notice.

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 John E. Fogarty International Center, the National Institutes of Health (NIH), 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: Assessing the Long-Term Impacts of the John E. Fogarty International Center's Research and Training Programs.

Type of Information Collection Request: New collection.

Need and Use of Information Collection: This study will inform investment decisions and strategies employed by the Fogarty International Center for the purpose of strengthening biomedical research capacity in low and middle income countries. The primary objective of the study is to develop detailed case studies of the long-term impacts of Fogarty's research and training programs on educational institutions located in low and middle income countries. The findings will provide valuable information concerning return on the Center's investments over the past twenty years and effective strategies for promoting research capacity development in the future.

Frequency of Response: Once.

Affected Public: Individuals.

Type of Respondents: Current and former NIH grantees; Current and former NIH trainees in countries of interest; Leaders and administrators at institutions of interest; Policy-makers and scientific leaders in countries of interest.

Estimated Number of Respondents: 105 per institution; total of 10 institutions over five years.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours per Response: 1 hour for interview participants; 2 hours for focus group participants.

Estimated Total Annual Burden Hours Requested: 290 and the annualized cost to respondents is estimated at $4,841.

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

	Number of respondents/ participants per institution	Number of institutions per year	Number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Interviews with U.S.-based principal investigators	20	2	1	1	40
Focus groups with selected trainees and follow-on survey	40	2	1	2	160
Interviews with university leadership	4	2	1	1	8
Interviews with trainees	13	2	1	1	26
Interviews with foreign grantees	20	2	1	1	40
Interviews with foreign policy-makers/scientific leaders	8	2	1	1	16
Total	105				290

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.

ADDRESSES: You may submit comments via regular mail to Dr. Linda Kupfer, Fogarty International Center, National Institutes of Health, 16 Center Drive, MSC 6705, Building 16, Room 202, Bethesda, MD 20892 or via electronic mail to *kupferl@mail.nih.gov.*

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. Linda Kupfer, Fogarty International Center, National Institutes of Health, 16 Center Drive, Building 16, Room 202, Bethesda, MD 20892, or call 301–496–1491 (this is not a toll-free number), or E-mail your request, including your address to: *kupferl@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: May 19, 2010.

Timothy J. Tosten,

Executive Officer, Office of Administrative Management and International Services, John E. Fogarty International Center, National Institutes of Health.

[FR Doc. 2010–12782 Filed 5–26–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency 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.

Simple, Quantitative and Highly Specific Antibody Detection of Lyme Disease

Description of Invention: This invention uses the Luciferase Immunoprecipitation System (LIPS) as a highly specific and high throughput method for diagnosing *Borrelia burgdorferi (Bb)* infection, a causative agent of Lyme disease. Many antigens, fused to the renilla luciferase (RUC) system, were tested for their ability to detect the disease; however, a novel synthetic protein called VOVO displayed the highest sensitivity and specificity of those tested. VOVO demonstrated 94% sensitivity and 100% specificity and markedly out-performed the C6 ELISA test (currently the most sensitive test available, with 76% sensitivity and 98% specificity) in an analysis of independent validation serum sets. Unlike the C6 ELISA, the VOVO LIPS assay displayed a wide dynamic range of antibody detection spanning over a 10,000-fold range without serum dilution. These results indicate that LIPS screening method using VOVO or other *Bb* antigens offer a more convenient, efficient and quantitative approach to serological screening of antibodies to Lyme disease.

The VOVO LIPS test may benefit from a large market as it could potentially become part of a routine screening panel for Lyme disease. In addition to its high sensitivity and specificity, the test also provides a rapid, simple and high-through-put approach for efficient screening of the disease. It may also be adapted for detection of *Borrelia* species endemic to other regions of the world.

Applications:

• Increased sensitivity and specificity for detection of Lyme disease.

• Rapid and convenient detection of Lyme disease.

Development Status: Early Stage.

Market: 29,000 new cases per year in the U.S.

Inventors: Peter D. Burbelo (NIDCR), Michael J. Iadarola (NIDCR), Adriana R. Marques (NIAID).

Publication: PD Burbelo *et al.* Rapid, Simple, Quantitative, and Highly Sensitive Antibody Detection for Lyme Disease. Clin Vaccine Immunol. 2010 Apr 14; Epub ahead of print, doi:10.1128/CVI.00476–09. [PubMed: 20392886]

Patent Status: U.S. Provisional Application No. 61/312,520 filed 10 Mar 2010 (HHS Reference No. E–036–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Susan Ano, PhD; 301–435–5515; *anos@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research, Laboratory of Sensory Biology, Neurobiology and Pain Therapeutics Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact David W. Bradley, PhD at 301–402–0540 or *bradleyda@nidcr.nih.gov.*

Software System for Processing and Analysis of Multi-Dimensional NMR Data

Description of Invention: Available for licensing is a software system useful in applications involving nuclear magnetic resonance (NMR). The software system, called NMRPipe, is written in the C programming language, and makes use of the TCL/TK scripting environment. The system includes over 500 modules for processing and analyzing experimental data of one to four dimensions collected on NMR spectrometers. The system exploits the UNIX computer operating system facilities of pipelines and scripts to link modules in a highly flexible, user-definable manner. NMR is a widely used analytical method, applied to both solution and solid state samples. The information obtained from such data pertains to the structure, motion, and interactions of molecular systems, including proteins, nucleic acids, and organic molecules.

Applications:

• Biomedical research for studying protein and nucleic acid structures and their interactions.

• Chemical applications involving synthesis, identification, or production of organic molecules.

Development Status:

• The software is mature.

• Binary executables of the software have been widely distributed, both to academic institutions as well as commercial organizations.

• The software is under active development.

• The software will be readily available upon request.

Inventors: Frank Delaglio (NIDDK).

Related Publications:

1. Kontaxis G, Delaglio F, Bax A. Molecular fragment replacement approach to protein structure determination by chemical shift and dipolar homology database mining. Methods Enzymol. 2005;394:42–78. [PubMed: 15808217]

2. Delaglio F, Wu Z, Bax A. Measurement of homonuclear proton couplings from regular 2D COSY spectra. J Magn Reson. 2001 Apr;149(2):276–281. [PubMed: 11318630]

3. Cornilescu G, Delaglio F, Bax A. Protein backbone angle restraints from searching a database for chemical shift and sequence homology. J Biomol NMR. 1999 Mar;13(3):289–302. [PubMed: 10212987]

4. Delaglio F, Grzesiek S, Vuister GW, Zhu G, Pfeifer J, Bax A. NMRPipe: a multidimensional spectral processing system based on UNIX pipes. J Biomol NMR. 1995 Nov;6(3):277–293. [PubMed: 8520220]

Patent Status: HHS Reference No. E–076–2009/0—Software. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, PhD, MBA; 301–435–4616; UR7a@nih.gov; or John Stansberry, PhD; 301–435–5236; *js852e@nih.gov.*

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the NMRPipe software system. Please contact Cindy Fuchs at 301–451–3636 or Frank Delaglio at *frankde@niddk.nih.gov* for more information.

Target Activated Microdissection—Kits and High Throughput Applications

Description of Invention: A variety of techniques have been used to microdissect specific cells or cell populations from a histological sample under direct microscopic visualization. Original microdissection techniques involved painstaking (and sometimes clumsy) manual dissection using needles or other micro-manipulation

devices to isolate individual cells based on visible, histological characteristics.

The subject technology is a novel method of performing specific target activated transfer from a biological sample (i.e. tissue) for analysis using a device system that can be automated for high throughput analysis or using benchtop kits. The method employs a localized reagent, such as an absorbative stain or immunoreagent that specifically determines the microadhesion of desired cellular material in a tissue sample to a transfer surface such as a thermoplastic polymer film. The energy from a light or heat source causes the specific microadhesion of the target cells or cell populations to the thermoplastic transfer surface without damage to the cells. Subsequent separation of the film from the tissue section selectively removes the adhered target from the tissue section. The method is specific and eliminates the need for direct manual visualization. Kits based on the method have the distinct advantage of not requiring expensive equipment; and thus, are a cost effective option for microdissection and analysis.

Applications:

• Microdissection and analysis kits for histological samples.

• High throughput analysis of biological samples.

Advantages:

• Does not require a visual detection step.

• Kits based on the method are low cost options for microdissection.

• Automated high throughput microdissection and analysis capabilities.

Development Status: In vitro data can be provided upon request.

Inventors: Michael R. Emmert-Buck (NCI), Robert F. Bonner (NICHD), *et al.*

Publications:

1. Tangrea MA, Chuaqui RF, Gillespie JW, Ahram M, Gannot G, Wallis BS, Best CJ, Linehan WM, Liotta LA, Bonner RF, Emmert-Buck MR. Expression microdissection: operator-independent retrieval of cells for molecular profiling. Diagn Mol Pathol. 2004 Dec;13(4):207–212. [PubMed: 15538110]

2. Grover A, Woodson KA, Tangrea MA, Wallis BS, Hanson J, Chuaqui RF, Gillespie JW, Erickson HS, Bonner RF, Pohida T, Emmert-Buck MR, Libutti SK. Tumor-associated endothelial cells display GSTP1 and RAR beta2 promoter methylation in human prostate cancer. J Translational Med. 2006 Mar 2;4:13. [PubMed: 16512911]

3. Hanson JC, Rodriguez-Canales J, Bonner RF, Pohida T, Tangrea MT, Emmert-Buck MR. Expression Microdissection Adapted to Commercial Laser Dissection Instruments (Submitted for publication).

Patent Status:

HHS Reference No. E–113–2003/0—

• U.S. Patent Application No. 10/543,218 filed 22 Jul 2005, allowed.

• U.S. Patent Application No. 12/753,566 filed 02 Apr 2010.

• Australian Patent 2003256803 issued 21 Jan 2010.

• Australian Patent Application No. 2009250964 filed 23 Jul 2009.

• Canadian Patent Application No. 2513646 filed 23 Jun 2003.

HHS Reference No. E–113–2003/1—

• U.S. Patent 7,695,752 issued 13 Apr 2010.

• U.S. Patent Application No. 12/713,105 filed 24 Feb 2010.

Licensing Status: Available for licensing.

Licensing Contact: Kevin W. Chang, PhD; 301–435–5018; *changke@mail.nih.gov.*

Therapeutic HIV Vaccine and Associated Protocols

Description of Invention: This technology describes a therapeutic HIV DNA vaccine to be administered to individuals who have previously experienced or are undergoing antiretroviral therapy (ART). The therapeutic DNA vaccine can also be administered in combination with a vector encoding an IL–15 and/or IL–15 receptor alpha (IL–15Ra) polypeptide. In primate studies, the technology was found to be particularly effective when the vaccine composition was administered by electroporation and expressed six (6) HIV antigens (including two (2) gag polypeptides and two (2) envelope polypeptides) and IL–15 and IL–15Ra. The antigens are typically modified with a destabilizing sequence, a secretory polypeptide and/or a degradation signal. Successive administration up to as many as nine resulted in continual boost of the immune response against the encoded antigen. A potent immunotherapeutic vaccine as described here could be an important technology for the fight against HIV/AIDS.

Applications: Therapeutic HIV DNA vaccines.

Development Status: Primate data available.

Inventors: Barbara Felber *et al.* (NCI).

Patent Status:

• U.S. Patent Application No. 12/522,775 filed 10 Jul 2009, claiming priority to 12 Jan 2007 (HHS Reference No. E–103–2007/0–US–03).

• U.S. Patent Application No. 12/160,263 filed 08 Jul 2008, claiming priority to 13 Jan 2006 (HHS Reference No. E–254–2005/2–US–12); and related international patent applications.

• U.S. Patent Application No. 11/571,879 filed 09 Jan 2007, claiming priority to 09 Jul 2004 (HHS Reference No. E–249–2004/1–US–02).

• U.S. Patent Application No. 12/426,901 filed 20 Apr 2009, claiming priority to 01 Nov 2000 (HHS Reference No. E–308–2000/0–PCT–02); and related international patent/patent applications.

Licensing Status: Available for licensing.

Licensing Contact: Kevin W. Chang, PhD; 301–435–5018; *changke@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HIV DNA vaccines. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

A Novel Chimeric Bifunctional Protein for Prevention and Treatment of HIV Infection

Description of Invention: This invention relates to bifunctional fusion proteins effective in HIV neutralization. Specifically, the invention is a genetically engineered chimeric protein composed of a soluble extracellular region of human CD4 (sCD4) attached via a flexible polypeptide linker to a single-chain construct of a human monoclonal antibody directed against a CD4-induced, highly conserved gp120 determinant involved in co-receptor interaction and virus entry. Mechanistically, the binding of the sCD4 moiety to the HIV gp120 Env glycoprotein induces a conformational change that enables the antibody moiety to bind, thereby blocking Env function and virus entry. This novel design provides the protein with unique characteristics that enables its extremely strong binding to gp120, thus rendering it a potential effective antiviral agent against HIV. Recent studies (Lagenaur *et al.* Retrovirology 7:11, 2010) indicate that this novel bispecific protein displays extremely broad neutralizing activity against genetically diverse primary HIV–1 isolates, with breadth much greater than previously described (Dey *et al.* J. Virology 77:2859, 2003). The potency is generally at least 10-fold greater than the best described HIV–1 neutralizing monoclonal antibodies, and the protein is highly active against many HIV–1 isolates that are refractory to neutralization by these antibodies. The bifunctional protein is comparably potent against isogenic virions produced from a human cell line versus PBMC; by contrast, the broadly-reactive monoclonal antibodies are much less

potent against virions produced from PBMC, perhaps due to differences in glycosylation. Importantly, the bifunctional protein is composed of almost entirely human sequences. It potentially can be linked to other functional moieties to achieve desired properties (longer plasma half-life, selective killing of HIV-infected cells, imaging of viral reservoirs, etc.).

The chimeric protein of this invention has considerable potential for prevention of HIV–1 infection, both as a topical microbicide and as a systemic agent to protect during and after acute exposure (*e.g.* vertical transmission, post exposure prophylaxis). It also has potential utility for treatment of chronic infection, including gene therapy strategies involving hematopoietic stem cells and/or viral vectors. Such proteins, nucleic acid molecules encoding them, and their production and use in preventing or treating viral infections are claimed in the patents issued for this invention.

Applications:

• Prophylactic and/or therapeutic treatment for HIV infection.

• Topical microbicide treatment to protect against HIV infection.

• Imaging of HIV infected cells in tissues.

Advantages:

• High neutralization efficiency due to unique bifunctional binding characteristics.

• Potentially minimally immunogenic or toxic (human sequences and possibly low treatment doses).

• Broad neutralizing activity.

• Mechanism of action less susceptible to resistance.

Development Status:

• Reproducible production and scale-up of chimeric protein has been demonstrated.

• Potent and broad neutralization of genetically diverse HIV–1 clinical isolates was demonstrated.

Market: The race to develop effective antiviral strategies against HIV infection is ongoing. The problems exhibited by conventional drugs such (i.e. toxicity and resistance) have triggered the pursuit of alternative approaches to HIV/AIDS prevention and treatment. One of the new approaches is the development of neutralizing antibodies against the HIV envelope proteins. This approach has not yet yielded any commercially viable treatment. It is believed that the approach presented in the subject invention will circumvent many of the shortcomings of the existing drugs and other pursued approaches. If this approach is successful the commercial rewards will be huge because of the global magnitude of HIV epidemics.

Inventor: Edward A. Berger (NIAID).

Related Publications:

1. Lagenaur LA, Villarroel VA, Bundoc V, Dey B, Berger EA. sCD4–17b bifunctional protein: Extremely broad and potent neutralization of HIV–1 pseudotyped viruses from genetically diverse primary isolates. Retrovirology 2010 Feb 16; 7:11. [PubMed: 20158904]

2. Dey B, Del Castillo CS, Berger EA. Neutralization of human immunodeficiency virus type 1 by sCD4–17b, a single-chain chimeric protein, based on sequential interaction of gp120 with CD4 and coreceptor. J Virol. 2003 March; 77(5):2859–2865. [PubMed: 12584309]

Patent Status:

HHS Reference No. E–039–1999/0—

• U.S. Patent No. 7,115,262, issued 03 Oct 2006.

• U.S. Application No. 11/535,957, filed 27 Sep 2006, published 18 Oct 2007 as 20070243208.

• Australian Patent No. 765218, issued 30 Jul 2003.

• European Patent No. 1161445 issued 03 Sep 2008 for France, Germany, Great Britain, Italy.

• Applications pending in Canada, Japan.

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, PhD, MBA; 301–435–4616; *ur7a@nih.gov;* or Susan Ano, PhD, 301–435–5515; *anos@mail.nih.gov*.

Collaborative Research Opportunity: The NIAID, Office of Technology Development, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize "A Novel Chimeric Protein for Prevention and Treatment of HIV Infection." Please contact Marguerite J. Miller at 301–435–8619 for more information.

Dated: May 20, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–12794 Filed 5–26–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency 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.

UOK 257, the First BHD Tumor Cell Line, and UOK257–2 Wild Type FLCN-Restored Renal Cell Line as *In Vitro* and *In Vivo* Models of Energy/Nutrient Sensing Through the AMPK and mTOR Signaling Pathways

Description of Invention: Scientists at the National Institutes of Health (NIH) have developed a novel renal cell carcinoma (RCC) cell line designated UOK257, which was derived from the surgical kidney tissue of a patient with hereditary Birt-Hogg-Dube' (BHD) syndrome and companion cell line UOK257–2 in which FLCN expression has been restored by lentivirus infection. These cell lines harbors a germline mutation of FLCN gene (alias BHD) and displays loss of heterozygosity, can grow as xenograft in nude mice. Patients affected with BHD develop skin papules (fibrofolliculomas), lung cysts, spontaneous pneumothorax and an increased risk for bilateral multifocal renal tumors. Loss of both copies of the FLCN gene has been documented in BHD renal tumors; however, the molecular mechanisms by which inactivation of the encoded protein, folliculin, leads to the BHD phenotype are currently unknown. They have developed an important research tool for in vitro folliculin functional studies. The companion cell line will be extremely useful for comparative biochemical analyses of cell culture systems in which the FLCN gene is either expressed or inactivated, including identification of renal tumor biomarkers, alteration of biochemical pathways resulting from loss of FLCN