Paperwork@hcfa.gov, or call the Reports Clearance Office at (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan (HCFA–R–267), Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 14, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–4568 Filed 2–23–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Study of Physician Researchers Concerning Research and Clinical Care Activities

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 Department of Clinical Bioethics, 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: Study of Physician Researchers Concerning Research and Clinical Care Activities. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* In order to understand the sometimes-conflicting obligations of physicians involved in clinical research, it is important to study their own understanding of their work and responsibilities as researchers and as clinicians treating patients. This study aims to gather this information through interviews with physicians involved in clinical research and other experts knowledgeable about their work. In particular, the study aims to identify and examine what physicians experience as the nature of the conflict between their roles as caregiver and researcher, physicians' most recent case of conflict between treatment and research, pressures on physicians involved in research and how they address or resolve them, conflict between caring for patients and gaining generalizable knowledge, and the influence of the work and institutional setting on physicians undertaking medical research. *Frequency of Response:* Once for the survey administration and for individuals interviewed and on occasion thereafter. *Affected Public:* Individuals. *Type of Respondents:* Physicians involved in clinical research and other interviewees knowledgeable about their practices. *Annual Reporting Burden:* The annual reporting burden follows in the table below. *Annualized Cost to Respondents:* The annualized cost to respondents is estimated at: $11,000. *Capital Costs:* There are no capital costs to report. *Operating or Maintenance Costs:* There are no operating or maintenance costs to report.

RESPONDENT AND BURDEN ESTIMATE INFORMATION

Type of respondents	Estimated number of respondents	Estimated number of response per respondent	Average burden hours per response	Estimated total annual burden hours requested
Physician Researchers	250	1	.5	125
Physician Researchers	80	1	1	80
Non-Physician-Researcher Interviewees	20	1	1	20
Total				225

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 CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Elaine Draper, Ph.D., J.D., Department of Clinical Bioethics, NIH, Building 10, Room 1C118F, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 435–8715 or E-mail your request, including your address to: *EDraper@nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received on or before April 27, 2001.

Dated: February 14, 2001.

David K. Henderson,

Deputy Director for Clinical Care.

[FR Doc. 01–4619 Filed 2–23–01; 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.

Coupled Calcium/Citrate Delivery System and Method for Apheresis Devices

Charles D. Bolan (CC), Susan F. Leitman (CC), Herb Cullis
DHHS Reference No. E–001–01/0 filed 03 Nov 2000
Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a method and device for eliminating the long recognized physiologic symptoms caused by the use of citrate anticoagulant in apheresis procedures. The adverse effects caused by citrate anticoagulants can be prevented by administration of an intravenous calcium infusion through the return line, coupled to the rate of the citrate infusion administered into the draw line of apheresis devices. The invention automatically couples the calcium infusion rate to the citrate anticoagulant rate. The device calculates and administers the appropriate amount of intravenous elemental calcium to neutralize citrate symptoms, and replaces calcium for donors and patients receiving citrate infusions during the performance of apheresis procedures. The invention fills a long standing need to make apheresis procedures safer, more economical, and more universally applicable to a wider range of donors. In addition, the invention significantly shortens the amount of time necessary for the apheresis procedure, by allowing higher flow rates.

Adaptive Sensitivity Encoding Incorporating Temporal Filtering (TSENSE)

Peter Kellman, Elliot McVeigh (NHLBI)
DHHS Reference No. E–200–00/0
Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is an accelerated magnetic resonance imaging method developed to reduce the total imaging time for gated, segmented cine imaging or to increase the frame rate when imaging dynamic activity, such as heart motion or brain activity. The invention combines temporal filtering (e.g., the UNFOLD method) with a known spatial sensitivity encoding technique (SENSE or SMASH) to achieve a new technique that is the subject of the invention (TSENSE) having a higher degree of alias artifact rejection than could be obtained using either temporal or spatial filtering individually. The new technique tracks changing coil sensitivities over time, which may arise due to chest wall or other body motions, and provides time saving by eliminating a separate reference acquisition. The invention is thus a robust accelerated imaging method that tolerates body motion or change in scan plane without the need to reacquire additional reference images, and the method may be used to reconstruct the full field-of-view with a large temporal bandwidth.

Endoluminal Radiofrequency Cauterization System

Bradford J. Wood (CC)
DHHS Reference No. E–244–00/0 filed 07 Dec 2000
Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a device for occluding the lumen of a hollow organ, vessel or aneurysm by delivering radio frequency energy to its inner wall. The apparatus uses specialized electrodes that contact the walls of the organ to substantially conform to the inner surface. RF energy is then applied to the electrode at any of a broad range of desired frequencies for selected times at power levels of from 20 to 200 watts. Delivery of RF energy may be regulated by monitoring temperature, tissue impedance or other parameters at or near the site of the electrode. A temperature sensor located near the electrode allows microprocessor-based control of the power delivered to the electrode site as a function of tissue temperature. The device has applications in therapeutic thrombosis of an aneurysm, stopping blood flow to a tumor or bleeding vessel, or reducing stricture or stenosis in, for example, a bronchus, esophagus, intestine segment or a blood vessel. The invention also may be useful in reducing stenosis in a coronary artery or to reduce a restenotic lesion from intimal hyperplasia that may occur after angioplasty.

Radio Frequency Probes for Tissue Treatment and Methods of Use

Bradford J. Wood (CC)
DHHS Reference No. E–186–00/0 filed 10 Jul 2000
Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a device and method for radio frequency (RF) treatment of tissue that is designed to destroy or damage selected tissue areas without damaging surrounding material. Improvements upon currently available techniques include: easier percutaneous deployment and placement, easier imaging visualization, less bleeding complications, and one-handed deployment. Applications include the treatment of metastatic cancer lesions in the liver, kidney or other solid internal organ. The invention can be used for minimally invasive procedures. For example, RF electrodes may be placed percutaneously to treat a cancer lesion in the liver. Standard medical imaging techniques such as ultrasound can be used to guide the RF electrode into the proper position, and surface markings made on the electrode improve the ultrasound visibility of the instrument. This invention is easily operated using only one hand, allowing the operator's other hand to be free to operate a medical imaging device or manage the delivery of the RF energy. The RF probe has an introducer that carries it to the desired site where a number of RF electrodes are deployed from the introducer into the subject's tissue. The RF electrodes may be deployed by a spring mechanism. The introducer has a biodegradable occluder that reduces tissue injury as the device is inserted into the subject. The occluder is displaced from the distal end of the introducer as the device transitions to a deployed state.

Modifications of HIV Env, Gag and Pol Enhance Immunogenicity for Genetic Immunization

Chakrabarti et al. (NIAID)
DHHS Reference Nos. E–275–00/0 filed 14 Aug 2000 and E–275–00/1 filed 14 Nov 2000
Licensing Contact: Carol Salata; 301/496–7735 ext. 232; e-mail: salatac@od.nih.gov

Protective immunity against human immunodeficiency virus-1 (HIV–1) is likely to require recognition of linear and conformation epitopes from multiple HIV antigens. This invention relates to modified HIV Env, Gag and Pol DNA and proteins with improved ability to elicit antibody and CTL responses. The Env DNA has been modified to expose the core protein for optimal antigen presentation and recognition. This invention also relates to a Gag-Pol fusion protein that is a polyprotein designed to maximize epitope presentation. The effect of

specific mutations in HIV–1 Env on humoral and cellular immune responses after DNA vaccination has been investigated. The modifications of Env enhance antibody production to this viral protein that may facilitate the generation of broadly neutralizing antibodies to HIV. In addition, the immune response to HIV–1 Gag and Pol after plasmid DNA immunization with Rev-independent expression vectors encoding various forms of these proteins has been examined. The Gag-Pol fusion protein induced the most broad and potent CTL responses to Gag and Pol in DNA-vaccinated mice. These DNA sequences and proteins may be important immunogens for the treatment and prevention of HIV infection.

Mucosal Cytotoxic T Lymphocyte Responses

Jay A. Berzofsky (NCI), Igor M. Belyakov (NCI), Michael A. Derby (NCI), Brian L. Kelsall (NIAID), Warren Strober (NIAID)
Serial Number 09/508,552 filed June 12, 2000; DHHS Reference No. E–268–97/4 filed January 10, 2001
Licensing Contact: Peter Soukas; 301/496–7056, ext. 268; e-mail: soukasp@od.nih.gov

This invention claims methods and compositions for inducing a protective mucosal cytotoxic T lymphocyte (CTL) response in a mammal involving administering a soluble antigen or a soluble antigen with one or more active agents such as a cytokine or co-stimulatory molecule to a mucosal surface or tissue. As a preferred embodiment, the invention contemplates intrarectal administration of the peptide vaccine because the inventors have shown that there is a greater CTL response through intrarectal administration rather than intranasal administration. The synthetic peptide vaccines utilized in the invention to elicit protective immune responses after mucosal infection comprise a multideterminant helper peptide containing a cluster of overlapping helper epitopes (a PCLUS or cluster peptide) colinearly synthesized with a peptide epitope target for neutralizing antibodies and CTL. The inventors have generated data showing that an intrarectally administered synthetic multiepitope HIV/SIV peptide vaccine administered to macaques in conjunction with mutant E. coli heat labile enterotoxin as an adjuvant induces mucosal CTL responses that provide better protection against intrarectal SHIV infection when compared to a subcutaneously administered vaccine comprising the same peptides inducing as high or higher systemic CTL responses. The invention is further described in Belyakov et al., Proc. Natl. Acad. Sci. USA 1998 Feb 17;95(4):1709–14 and Belyakov et al., J. Clin. Invest. 102: 2072–2081, 1998.

A Novel Chimeric Protein for Prevention and Treatment of HIV Infection

Edward A. Berger (NIAID), Christie M. Del Castillo
Serial No. 60/124,681 filed 16 Mar 1999 and PCT/US00/06946 filed 16 Mar 2000
Licensing Specialist: Peter Soukas; 301/496–7056 ext. 268; e-mail: soukasp@od.nih.gov

This invention relates to bispecific fusion proteins effective in viral neutralization. Specifically, the invention is a genetically engineered chimeric protein containing a soluble extracellular region of human CD4 attached via a flexible polypeptide linker to a single chain human monoclonal antibody directed against a CD4-induced, highly conserved HIV gp120 determinant involved in coreceptor interaction. Binding of the sCD4 moiety to gp120 induces a conformational change that enables the antibody moiety to bind, thereby blocking Env function and virus entry. This novel bispecific protein displays neutralizing activity against genetically diverse primary HIV–1 isolates, with potency at least 10-fold greater than the best described HIV–1 neutralizing monoclonal antibodies. The agent 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. Such proteins, nucleic acid molecules encoding them, and their production and use in preventing or treating viral infections are claimed.

Antimicrobial Magainin Peptides

Michael A. Zasloff, Hao-Chia Chen, Judith H. Brown, John L. Morell, Charng-Ming Huang (NICHD)
Serial No. 07/280,363 filed 12/06/1988, now U.S. Patent 5,221,732; Serial No. 07/021,493 filed 03/04/1987, now U.S. Patent 4,810,777; Serial No. 07/834,992 filed 02/14/1992, now U.S. Patent 5,567,681; Serial No. 07/963,007 filed 10/19/1992, now U.S. Patent 5,643,876
Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; e-mail: soukasp@od.nih.gov

First isolated from the skin of the African clawed frog *Xenopus laevis*, magainin peptides have been shown by the inventors to have broad-spectrum antimicrobial properties. Both synthetic and natural magainin peptides are active against many species of bacteria and fungi and induce osmotic lysis of protozoa. Magainin peptides are water soluble, nonhemolytic at effective antimicrobial concentrations, have molecular weights of 2500 or less and are amphiphilic. Compositions and methods for their use are claimed in the patents. These inventions are available for nonexclusive or exclusive licensing. The inventions are further described in Zasloff et al., P.N.A.S. USA 1987 Aug.;84(15):5449–53; Marion et al., FEBS Lett. 1988 Jan.18;227(1):21–6; Soravia et al., FEBS Lett. 1988 Feb. 15;228(2):337–40; Westerhoff et al., P.N.A.S. USA 1989 Sep.;86(17):6597–601; and Gwadz et al., Infect. Immun. 1989 Sep.; 57(9):2628–33.

Dated: February 15, 2001.

Jack Spiegel,

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

[FR Doc. 01–4616 Filed 2–23–01; 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, 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.

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Plasmids Expressing START Domains of StAR and MLN64

Dr. Yosuke Tsujishita and Dr. James Hurley (NIDDK)
DHHS Reference No. E–020–01/0
Licensing Contact: Marlene Shinn; 301/496–7056 ext. 285; e-mail: shinnm@od.nih.gov