the data collector, age-eligible women residing in the tertiary sampling units would also be invited to participate in the high intensity data collection, which is the current Vanguard Study protocol. If a woman eligible to participate in the high intensity collection effort declines, she may continue participating in the low intensity effort.

Based on data collected to date, and assuming no household enumeration or provider-referrals, we anticipate that the secondary sampling units would need to be three times larger than the original Vanguard Study secondary sampling units to identify the required number of pregnant women within the Study's timeframe. Accordingly, assuming age-sex eligible targets three times larger than those in the original Vanguard Study proposal, an approximate 80% participation rate to the initial screener, an approximate 65% consent rate to minimal, self-administered data collection at approximately 30 minutes each 6 month period, less enumeration effort and efficiencies in other aspects of field work based on field experience, we estimate the low intensity tier recruitment strategy will require 78,222 respondent burden hours over the first two years of data collection. For the high intensity tier strategy, assuming respondent burden estimates from the original Vanguard Study proposal, less enumeration efforts and efficiencies gained from field experience, we estimate this recruitment strategy will require 27,800 respondent burden hours over the first two years of data collection. Combined, this recruitment strategy would require approximately 106,022 respondent burden hours over a two year period. (For reference, the original Vanguard Study proposed expending 37,042 respondent burden hours for the same data collection period.)

There are several goals of this recruitment strategy that recommend it despite comparatively higher estimated respondent burden. The two-tier strategy allows the opportunity to engage women participating in the low intensity data collection effort and build trust before participants are asked to consider joining the high intensity effort. This aspect may increase the likelihood of participation in the high intensity data collection (that is, the full protocol) as compared to the other alternate recruitment strategies. This strategy also fits within the existing probability-based sampling frame for the Main Study. Women that decide to leave the high intensity data collection may remain within the study in a structured context in the low intensity setting. Additionally, the two-tier strategy offers a means to gauge the size of geographic areas that might be necessary for reaching alternative enrollment targets and to systematically compare bias in enrollment between high and low intensity groups—analyses that will benefit the design of the Main NCS study regardless of which recruitment strategies are ultimately chosen.

Frequency of Response: See above descriptions.

Affected Public: Pregnant women and their children

The annualized cost to respondents over the two year data collection period for all three recruitment strategies combined is estimated at $1,660,520 (based on $10 per hour). There are no Capital Costs to report. There are no Operating 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 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. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland 20892, or call non-toll free number (301) 496–1877 or e-mail your request, including your address, to *glavins@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: March 18, 2010.

Sarah L. Glavin,

Deputy Director, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development, National Institutes of Health.

[FR Doc. 2010–6434 Filed 3–23–10; 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.

Novel Regulatory B Cells for Treatment of Cancer and Autoimmune Disease

Description of Invention: The manner by which cancers evade the immune response is not well-understood. What is known is that the manner is an active process that regulates immune responses employing at least two types of suppressive cells, myeloid-derived suppressive cells and regulatory T cells (Tregs), a key subset of $CD4^+$ T cells that controls peripheral tolerance to self- and allo-antigens. Tregs are considered to play a key role in the escape of cancer cells from anti-tumor effector T cells.

Cancer cells have been found to directly activate resting B cells to form suppressive regulatory B cells (tBregs) and utilize them to evade immune surveillance and mediate metastasis. tBregs directly inhibit $CD4^+$ and $CD8^+$ T cell activity in a cell contact-dependent

manner, induce FoxP3+ T cell activity, and promote Treg-dependent metastasis.

Researchers from the National Institute on Aging (NIA), NIH, have developed methods for the generation of tBregs, and for using tBregs to produce Tregs, and methods that inactivate or deplete tBregs. These methods have significant therapeutic value in the combat with cancer immune escape and metastasis, and in the control of harmful autoimmune diseases.

Applications:

- Production of cellular cancer vaccines.
- Treatments for immune-mediated disorders.
- Treatments for cancer.
- Treatments for chronic viral infections.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Arya Biragyn and Purevdorj Olkhanud (NIA).

Patent Status: U.S. Provisional Application No. 61/302,074 filed 05 Feb 2010 (HHS Reference No. E–101–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Patrick P. McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov*.

Collaborative Research Opportunity: The Immunotherapeutics Unit, National Institute on Aging, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the utilization of regulatory B cells to control autoimmune diseases and strategies that inactivate tBregs to control cancer immune escape. Please contact Nicole Darack, Ph.D. at 301–435–3101 or *darackn@mail.nih.gov* for more information.

A New Transmission Blocking Vaccine for Leishmania Infection

Description of Invention: A novel transmission blocking vaccine has been developed that can eliminate or reduce the number of *Leishmania chagasi* parasites in the gut of the sand fly species, *Lutzomyia longipalpis.* The vaccine involves the production of antibodies to the sand fly midgut protein, LP1, which is normally expressed in the midgut of the sand fly during a blood meal. This vaccine could potentially block parasite transmission from the sand fly to mammalian hosts and significantly reduce the incidence of leishmaniasis in endemic areas of the world such as Brazil, India, and Indonesia where leishmaniasis accounts for over 58,000 deaths annually.

Studies have shown that LP1 antibodies produced by immunized mice are able to reduce the number of *L. chagasi* parasites that develop in the midgut of *Lu. longipalpis.* These results illustrate the potential use of the protein as a vaccine to immunize dogs and protect humans from visceral leishmaniasis transmitted by the sand flies that feed on the infected, vaccinated dogs. In endemic areas such as Brazil where dogs are the principal reservoir for *L. chagasi,* the LPl antigen alone or in combination with other sand fly midgut proteins could be used to immunize household pets and stray dogs. Vaccinated dogs will produce antibodies to LPl, and once a sand fly feeds on blood from the infected and vaccinated dogs, the antibodies will inhibit development of the parasite in the gut of the sand fly. This approach can effectively block Leishmania transmission to human hosts. Such vaccines have the potential to reduce the risk of humans acquiring leishmaniasis without the risks involved in human vaccination.

Applications:

- Transmission blocking vaccine for Leishmania infection.
- Vaccination of dogs as reservoirs for the Leishmania parasite.

Development Status: Early stage.

Market: 500,000 cases of visceral leishmaniasis annually worldwide and 58,000 deaths in Brazil, Bangladesh and Nepal.

Inventors: Ryan C. Jochim and Jesus G. Valenzuela (NIAID).

Related Publication: Jochim RC, Teixeira CR, Laughinghouse A, Mu J, Oliveira F, Gomes RB, Elnaiem DE, Valenzuela JG. The midgut transcriptome of Lutzomyia longipalpis: comparative analysis of cDNA libraries from sugar-fed, blood-fed, post-digested and Leishmania infantum chagasi-infected sand flies. BMC Genomics. 2008 Jan 14;9(1):15. [PubMed: 18194529]

Patent Status: U.S. Provisional Application No. 61/265.250 filed 29 Oct 2009 (HHS Reference No. E–305–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James; 301–435–5474; *jeffreyja@mail.nih.gov*.

Collaborative Research Opportunity: The NIAID, OTD is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize "*A New Transmission Blocking Vaccine for Leishmania Infection*". Please contact Dana Hsu at 301–496–2400 for more information.

A Composition for Cyropreservation and Storage of Human Cellular Products

Description of Invention: This technology is directed to an enhanced composition for the freezing and storage of human cellular products for future use. The inventors have discovered optimal ratios of an extracellular cryoprotectant (low molecular weight pentastarch), an intracellular cryoprotectant (dimethyl sulfoxide, DMSO), and human serum albumin in a plasmalyte A solution. In comparison to currently available products, utilization of this composition results in a cryopreserved product with higher cell yield, longer period of viability and decreased incidence of dimethyl sulfoxide-related adverse effects.

Applications and Advantages:

- Cryopreservation and storage of human and other mammalian cellular products.
- Higher cell yield.
- Extended post-thaw viability.
- Decreased incidence of DMSO-related adverse effects.

Development Status: Early stage.

Market: This invention may be of interest to cell processing and storage companies, hospitals, and research institutions.

Inventors: Joseph F. Gallelli (CC) *et al.*

Patent Status: U.S. Provisional Application No. 61/256,075 filed 29 Oct 2009 (HHS Reference No. E–285–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@nih.hhs.gov.*

Polarization Adapter for Colposcope

Description of Invention: The invention offered for licensing is directed to a polarization adaptor for colposcopes. The colposcope is a medical diagnostic device that examines an illuminated magnified view of a patient's cervical, vaginal, and vulva tissues during a colposcopy procedure. Specifically, the invention provides for a specialized polarized camera (polarization adaptor) for integration into commercially available colposcopes. The addition of polarization to currently available colposcope results in an enhanced image video output that allows the user to view hidden subsurface tissue structures and textures, thereby allowing for better diagnosis of pathological conditions.

The device which can readily be adapted to commercial colposcope enables the separation of specularly

reflected light from diffusely backscattered light, coming from deeper tissue layers. In combination with suggested data processing algorithm, based on correlation analysis, this allows one to enhance imaging of the hidden subsurface tissue structure (texture).

Applications:

• The polarization adaptor of the invention can enhance the quality of imaging and diagnostics of conventional colposcope and thus improve early detection of pathologies, especially the status of the collagen network beneath the surface of the cervix.

• Screening and diagnostics of cervical abnormalities which can lead to cancer or pre-term delivery.

Advantages:

• Improved characterization of cervical tissue for better diagnosis of abnormalities in cervical, vaginal, and vulva tissues. Minimally invasive measurement and analysis of diffusely backscattered light using specific image processing procedures as provided in the invention, may contribute useful information about internal structures of biological tissues in more detail as compared with existing methods.

• The device can improve early detection of cervical cancer and thus save lives. Recent large-scale National Cancer Institute-sponsored clinical trial demonstrated that colposcopy failed to detect 33% of high-grade precancerous lesions in women referred with questionable Pap results. An improvement in detection capabilities is thus very much needed (*http://biomedreports.com/articles/most-popular/12449-non-invasive-device-for-cervical-cancer*).

• Enhanced diagnostics may result in the reduction of repeat examinations usually used for a definitive diagnostics for cervical cancer. Thus it may have favorable impact on healthcare costs.

• Can be readily adapted to any conventional colposcope.

Development Status:

• A working prototype was built.

• Need to gather clinical data and demonstrate clinical utility.

Market:

• Colposcopy is now routinely used for diagnostics of cervical cancer and other tissue abnormalities in female organs.

• In the U.S. alone, over $6 billion is spent annually on the screening, diagnosis and treatment of women with cervical cancer. Diagnosing cervical cancer is often a long and uncertain process requiring repeat visits to the Doctor's office. Approximately three (3) million colposcopy procedures are performed annually, with many repeat exams aimed at a definitive diagnosis. The U.S. colposcopy market alone is approximately $1 billion annually (*http://biomedreports.com/articles/most-popular/12449-non-invasive-device-for-cervical-cancer*).

• The repeat examinations typically required to arrive at a definitive determination are both stressful and expensive. For women with precancerous lesions, the long diagnostic cycle can allow the disease to progress and develop into invasive, life-threatening cancers. By providing a more definitive test, the device offered in this invention will allow clinicians to more effectively manage and treat millions of women who are at risk of cervical cancer.

In light of the above it is evident that a device that can be adapted to conventional instruments and provide for improved diagnostics will also be commercially rewarding.

Inventors: Amir H. Gandjbakhche *et al.* (NICHD).

Related Publications:

1. Jacques SL, Roman JR, Lee K. Imaging superficial tissues with polarized light. Lasers Surg Med. 2000;26(2):119–129. [PubMed: 10685085].

2. Jacques SL, Ramella-Roman JC, Lee K. Imaging skin pathology with polarized light. J Biomed Opt. 2002 Jul 7;7(3):329–340. [PubMed: 12175282].

3. Ramella-Roman JC, Lee K, Prahl SA, Jacques SL. Design, testing, and clinical studies of a handheld polarized light camera. J Biomed Opt. 2004 Nov–Dec;9(6):1305–1310. [PubMed: 15568952].

4. Sviridov AP, Ulissi Z, Chernomordik V, Hassan M, Boccara AC, Gandjbakhche A, "Analysis of Biological Tissue Textures Using Measurements of Backscattered Polarized Light"; OSA Topical Meeting on Biomedical Optics, c.WD8 (2006).

5. Sviridov AP, Ulissi Z, Chernomordik V, Hassan M, Gandjbakhche A. Visualization of biological texture using correlation coefficient images. J Biomed Opt. 2006 Nov–Dec;11(6):060504. [PubMed: 17212522].

6. Sviridov AP, Chernomordik V, Hassan M, Boccara AC, Russo A, Smith P, Gandjbakhche A. Enhancement of hidden structures of early skin fibrosis using polarization degree patterns and Pearson correlation analysis. J Biomed Opt. 2005 Sep–Oct;10(5):051706. [PubMed: 16292958].

Patent Status: U.S. Provisional Application No. 61/242,652 filed 15 Sep 2009, entitled "Polarization Adapter for Colposcope" (HHS Reference No. E–161–2009–0–US–01).

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, Ph.D., MBA; 301–435–4616; *UR7a@nih.gov*; or Michael Shmilovich, J.D.; 301–435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The Eunice Shriver National Institute of Child Health and Human Development, Section on Analytical and Functional Biophotonics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the polarization camera for cervical tissue characterization. Please contact Joseph Conrad, Ph.D. at 301–435–3107 or *jmconrad@mail.nih.gov* for more information.

Dated: March 16, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–6433 Filed 3–23–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Medical Device Epidemiology Network: Developing Partnership Between the Center for Devices and Radiological Health and Academia; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Medical Device Epidemiology Network (MDEpiNet): Developing Partnership Between the Center for Devices and Radiological Health and Academia." The purpose of the public workshop is to facilitate discussion among FDA and academic researchers with expertise in epidemiology and health services research on issues related to the methodology for studying medical device performance.

Date and Time: The public workshop will be held on April 30, 2010, from 8 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Security screening will begin at 7 a.m., and registration will begin at 7:30 a.m.

Location: The public workshop will be held at the FDA White Oak Campus,