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,

10903 New Hampshire Ave., Silver Spring, MD 20993.

Contact: Kristen Van Dole, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6334, email: *Kristen.VanDole@fda.hhs.gov*; or Mary Beth Ritchey, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 307–796–6638, email: *MaryElizabeth.Ritchey@fda.hhs.gov*.

Registration: Email your name, title, organization affiliation, address, and email contact information to Kristen Van Dole (see *Contact*) by April 19, 2010. There is no fee to attend the public workshop, but attendees must register in advance. Registration will be on a first-come, first-served basis and we ask that one person per institution be selected to represent the entity at the workshop. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. If you need special accommodations because of a disability, please contact Mary Beth Ritchey (see *Contact*) at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to facilitate discussion among FDA and the academic epidemiology and health services research community on issues related to the methodology of studies for medical device performance.

We aim to reach out to academic centers that have epidemiologic, statistical, and clinically relevant expertise to establish a network that will work with FDA experts to determine the evidence gaps and questions, datasets and approaches for conducting robust analytic studies and improve our understanding of the performance of medical devices (including comparative effectiveness studies). The centers participating in the network will be expected to take part in other FDA-hosted scientific workshops that address methods for medical device comparative analyses, best practices and best design and analysis methods.

II. Who is the Target Audience for This Public Workshop? Who Should Attend This Public Workshop?

This workshop is open to all interested parties. The target audience is comprised of academic researchers with experience in epidemiology or health services research with an interest in medical device outcome and epidemiologic study methodology.

III. What Are the Topics We Intend to Address at the Public Workshop?

We intend to discuss a large number of issues at the workshop, including, but not limited to:

- Gaps and challenges in medical device outcomes and epidemiologic studies;
- Creation of the Medical Device Epidemiology Network (MdEpiNet) infrastructure; and
- Opportunities for medical device epidemiologic research and partnerships between CDRH and Academia.

IV. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/cdrh/meetings.html*.

Dated: March 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6446 Filed 3–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: AMCB and ADDT.

Date: March 31, 2010.

Time: 11 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mary Clare Walker, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov*.

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. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 16, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–6435 Filed 3–23–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Reproductive Biology.

Date: April 6–7, 2010.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)

Contact Person: Robert Garofalo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6156, MSC 7892, Bethesda, MD 20892, 301–435–1043, *garofalors@csr.nih.gov*.

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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Brain Disorders.

Date: April 15–16, 2010.

Time: 10 a.m. to 5 p.m.