

identification of viral epitopes is critically important to understanding immune responses to infection and vaccination, and there are currently no comparable methods besides the classic screening of vast arrays of overlapping viral peptides on blood lymphocytes. Peptide screening methods only identify possible target epitopes, but do not define which epitopes are expressed in lung tissue. The technology will be valuable for vaccine development and evaluation, and has the flexibility to allow rapid analysis of novel pandemic strains for immunogenic epitopes. The technology can be applied to other infectious diseases, cancer, and immunotoxicities.

## II. Award Information/Funds Available

### A. Award Amount

Only one grant award will be made in fiscal year (FY) 2012. The application budget is not limited, but it needs to reflect the actual needs of the proposed project. However, presently for FY 2012, the funds are available in the amount of \$400,000 (total cost), and are subject to change based on the availability of funds.

### B. Length of Support

The maximum period is 1 year with the option of 4 more years of budget support depending on the availability of funds.

## III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm088761.htm>. Persons interested in applying for a grant may obtain an application at <http://grants2.nih.gov/grants/funding/phs398/phs398.html>. For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number.
- Step 2: Register With Central Contractor Registration.
- Step 3: Register With Electronic Research Administration (eRA) Commons.

Steps 1 and 2, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 3, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit paper applications to: Gladys Bohler, Grants Management Specialist (see **FOR FURTHER INFORMATION CONTACT** section of this document).

Dated: August 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Dialogues in Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following Office of Women's Health and Society for Women's Health Research jointly sponsored meeting: Dialogues in Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials. The purpose of this symposium is to facilitate the broader discussion and dissemination of innovative strategies for increasing the recruitment and retention of women and minority subpopulations into clinical trials. The overarching goal of this symposium is to use a best practices learning exchange to share information and encourage successful methods and/or model implementation within a broad research community—industry, academia, and government.

**Date and Time:** The meeting will be held on September 22, 2011, from 8 a.m. to 9 a.m. (registration); 9 a.m. to 5:30 p.m. (program); 5:30 p.m. to 6:30 p.m. (reception); and September 23, from 8 a.m. to 1:30 p.m.

**Location:** The meeting will be held at L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024.

**Contact:** Deborah Kallgren, FDA Office of Women's Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2314, Silver Spring, MD 20993-0002, 301-796-9442, Fax: 301-847-8604, e-mail: [deborah.kallgren@fda.hhs.gov](mailto:deborah.kallgren@fda.hhs.gov).

**Registration:** Registration is free, but seating is limited to 200. Registration will be accepted online and is available at <http://www.swhr.org> through September 16, 2011. For information regarding registration contact: Rachel Griffith, Society for Women's Health Research (SWHR), 1025 Connecticut Ave., NW., Suite 701, Washington, DC 20036, 202-496-5001, Fax: 202-833-3472, e-mail: [rachel@swhr.org](mailto:rachel@swhr.org).

If you need special accommodations due to a disability, please contact Rachel Griffith at least 7 days in advance.

Dated: August 12, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-21042 Filed 8-17-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, codified at 5 U.S.C. App. 2), notice is hereby given of the following meeting:

**Name:** Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

**Dates and Times:** September 22, 2011, 8:30 a.m. to 5 p.m.; September 23, 2011, 8:30 a.m. to 3:30 p.m.

**Place:** Renaissance Washington, DC DuPont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

**Status:** The meeting will be open to the public with attendance limited due to space availability. Participants are asked to register for the meeting by going to the registration Web site at <http://altarum.cvent.com/event/SACHDNC092011>. The registration deadline is Tuesday, September 20, 2011. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate their needs on the registration website. The deadline for special accommodation requests is Friday, September 19, 2011. If there are technical problems gaining access to the Web site, please contact Maureen Ball, Meetings Coordinator, at [conferences@altarum.org](mailto:conferences@altarum.org).

**Purpose:** The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) was established by Congress to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having (or at risk) for heritable disorders. The Advisory Committee, as authorized by Public Law 106-310, which added

section 1111 of the Public Health Service Act, codified at 42 U.S.C. 300b-10, also provides advice and recommendations concerning grants and projects authorized under section 1109 of the Public Health Service Act (42 U.S.C. 300b-8).

**Agenda:** The meeting will include a review and reflection of the previous 24 meetings and a look forward. The agenda will include topics related to the past, present, and future work of the Committee, including: (1) A presentation of the previous, current and future endeavors of the External Review Workgroup's activities; (2) an update from the Evidence Evaluation and Methods workgroup's progress on developing the Decision Process Tree; (3) review of previous reports, workgroups and publications from the Committee and next steps for public health genetics; and (4) discussion and presentations on the previous and continued work and reports of the Advisory Committee's subcommittees on laboratory standards and procedures, follow-up and treatment, and education and training. Proposed agenda items are subject to change as priorities dictate. You can locate the Agenda, Committee Roster and Charter, presentations, and meeting materials at the home page of the Advisory Committee's Web site at <http://www.hrsa.gov/heritabledisorderscommittee/>.

**Public Comments:** This meeting will include an extended public comment period during the morning session on September 22, 2011. Members of the public can submit written comments and/or present oral comments during the public comment period of the meeting. Those individuals who want to make oral comments are requested to register online by Tuesday, September 20, 2011, at <http://altarum.cvent.com/event/SACHDNC092011>. Requests should contain the name, address, telephone number, and any professional or business affiliation of the person desiring to make an oral comment. Groups having similar interests are requested to combine their comments and present them through a single representative. Written comments should be e-mailed no later than Tuesday, September 20, 2011 for consideration. Oral and written public comment will be included in the transcripts of the meeting and will be posted to the committee's Web site. Written comments should contain the name, address, telephone number, and any professional or business affiliation of the author. Submit written comments to Maureen Ball, Meetings Coordinator, Conference and Meetings Management, Altarum Institute, 1200 18th Street,

NW., Suite 700, Washington, DC 20036, telephone: 202 828-5100; fax: 202 785-3083, or e-mail: [conferences@altarum.org](mailto:conferences@altarum.org).

**Contact Person:** Anyone interested in obtaining other relevant information should write or contact Alaina M. Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-0721, [aharris@hrsa.gov](mailto:aharris@hrsa.gov). More information on the Advisory Committee is available at <http://mchb.hrsa.gov/heritabledisorderscommittee>.

Dated: August 12, 2011.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

[FR Doc. 2011-21092 Filed 8-17-11; 8:45 am]

**BILLING CODE 4165-15-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.

#### Quantitative Measurement of Syndesmophytes in Ankylosing Spondylitis Using Computed Tomography (CT)

**Description of Technology:** Syndesmophyte (abnormal bone) growth in the spine is a hallmark of Ankylosing Spondylitis, a type of inflammatory

arthritis. Syndesmophyte growth is currently monitored using semi-quantitative scoring of radiographs, but radiographs consider only a small part of the vertebra, and the method is subject to reader error. Because syndesmophytes grow slowly, radiographs also lack sensitivity. The invention provides a method to measure syndesmophytes using data from computed tomography scans of the lumbar spine. It provides computer algorithm that fully quantitates syndesmophyte volumes in three-dimension space. This method allows precise and accurate measurement of the presence and rate of growth of syndesmophytes over time, which for the first time will permit testing of whether any treatments can slow the progression of this type of spinal arthritis.

#### Potential Commercial Applications:

- The method would be useful for clinical trials of drugs against Syndesmophyte growth.
- Because of the improved precision, achieving statistical significance in assessing the efficacy of a drug would require smaller samples.

#### Competitive Advantages:

- The present method is more automated than existing methods.
- The method is more precise and sensitive than existing methods, thus providing more reliable statistical analysis and improved planning in treatment regimen.

**Development Stage:** In vivo data available (human).

**Inventors:** Sovira Tan (NIAMS), *et al.*

**Publication:** Tan S, Yao J, Ward MM, Yao L, Summers RM. Computer aided evaluation of ankylosing spondylitis using high-resolution CT. *IEEE Trans Med Imaging* 2008 Sep;27(9):1252-1267. [PMID 18779065].

**Intellectual Property:** HHS Reference No. E-167-2011/0—Software. Patent protection is not being pursued for this technology.

**Licensing Contact:** Michael Shmilovich, *Esq.*; 301-435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

**Collaborative Research Opportunity:** The National Institute of Arthritis and Musculoskeletal and Skin Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Brian W. Bailey, Ph.D. at [bbailey@mail.nih.gov](mailto:bbailey@mail.nih.gov).