

abundant secreted proteins from the salivary glands of the sand fly *Lutzomyia longipalpis*, vector of *Leishmania chagasi*. *J Exp Biol*. 2004 Oct; 207(Pt 21):3717–3729. [PubMed: 15371479]

3. Valenzuela JG, Belkaid Y, Garfield MK, Mendez S, Kamhawi S, Rowton ED, Sacks DL, Ribeiro JM. Toward a defined *anti-Leishmania* vaccine targeting vector antigens: Characterization of a protective salivary protein. *J Exp Med*. 2001 Aug 6; 194(3):331–342. [PubMed: 11489952]

4. Belkaid Y., Valenzuela JG, Kamhawi S., Rowton E., Sacks DL, Ribeiro JM. Delayed-type hypersensitivity to Phlebotomus papatasi sand fly bite: An adaptive response induced by the fly? *Proc Natl Acad Sci U S A*. 2000 Jun 6; 97(12):6704–6709. [PubMed: 10841567]

Patent Status

- U.S. Patent Application No. 60/422,303 filed October 29, 2002 (HHS Ref. No. E-285-2002/0-US-01).
- PCT Application No. PCT/US2003/03453 filed October 29, 2003 (HHS Ref. No. E-285-2002/0-PCT-02). Application filed in the following countries: the USA, Europe, Brazil, Japan, Mexico, India and Israel.
- U.S. Patent No. 7,485,386 issued February 3, 2009 (HHS Reference No. E-285-2002/0-US-03).
- European Patent Number No. 1572968 issued April 22, 2009 (HHS Reference No. E-285-2002/0-EP-04).
- PCT Application No. PCT/US2009/042980 filed May 05, 2009 (HHS Reference No. E-189-2008/2-PCT-01).
- U.S. Patent Application No. 60/421,327 filed September 19, 2002 (HHS Ref. No. E-130-2002/0-US-01).
- PCT Application No. PCT/US03/29833 filed September 18, 2003 (HHS Ref. No. E-130-2002/0-PCT-02). Application filed in the following countries: USA, Europe, Brazil, Japan, Mexico, India and Israel.

Licensing Status: Available for licensing.

Licensing Contact: John Stansberry, PhD; 301-435-5236; stansbej@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 “Vaccines Comprising Sand Fly Salivary Proteins for Control of Leishmania Infection”. Please contact Dana Hsu at 301-451-3521 for more information.

Dated: May 26, 2010.

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

[FR Doc. 2010-13480 Filed 6-3-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0406]

Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs; Frequently Asked Questions—Statement of Investigator (Form FDA 1572); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an information sheet guidance entitled, “Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs; Frequently Asked Questions—Statement of Investigator (Form FDA 1572).” This guidance is intended to assist sponsors, clinical investigators, and institutional review boards (IRBs) involved in clinical investigations of investigational drugs and biologics in completing the Statement of Investigator form (Form FDA 1572). FDA developed this information sheet guidance in response to numerous questions from the research community regarding Form FDA 1572. This information sheet guidance provides FDA’s responses to the most frequently asked questions.

DATES: Submit either written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), 10903 New Hampshire Ave., Silver Spring, MD 20993 or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the information sheet guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph Salewski, Division of Scientific

Investigations, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring MD 20993, 301-796-3395.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an information sheet guidance entitled, “Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs; Frequently Asked Questions—Statement of Investigator (Form FDA 1572).” This guidance is intended to assist sponsors, clinical investigators, and IRBs involved in clinical investigations of investigational drugs and biologics in complying with the requirement that each investigator complete and sign a Form FDA 1572 before participating in an investigation. This guidance describes how to complete the Statement of Investigator form (Form FDA 1572).

FDA developed this information sheet guidance in response to numerous questions from the research community regarding the Form FDA 1572. In this guidance, we provide answers to frequently asked questions concerning the purpose of this form, when this form needs to be completed and signed by the investigator, how to best complete the various blocks within the form, and when the form might need to be updated. In addition, we clarify questions related to the use of Form FDA 1572 by clinical investigators participating in studies conducted outside the United States that may or may not be under an investigational new drug application.

This information sheet guidance is part of the Information Sheet Guidance Initiative, announced on February 3, 2006, in the **Federal Register** (71 FR 5861), which describes FDA’s intention to update the process for developing, issuing, and making available guidances intended for IRBs, clinical investigators, and sponsors. Known as “Information Sheets,” these guidances have provided recommendations to IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by the FDA since the early 1980s. The Information Sheet Guidance Initiative is intended to ensure that the Information Sheets are consistent with the FDA’s good guidance practices (GGPs). As part of the initiative, which will be ongoing, the agency plans to rescind Information Sheets that are obsolete, revise and reissue Information Sheet Guidances that address current issues, and develop

new Information Sheet Guidances as needed.

In the **Federal Register** of July 29, 2008 (73 FR 43940), FDA announced the availability of a draft version of the guidance entitled, "Draft Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs; Frequently Asked Questions—Statement of Investigator (Form FDA 1572)." The July 2008 guidance gave interested persons an opportunity to submit comments through September 29, 2008. All comments received during the comment period have been carefully reviewed and, where appropriate, incorporated in the guidance. As a result of the public comments and editorial changes, the guidance is clearer than the draft version.

This information sheet guidance is being issued consistent with FDA's GGP's regulation (21 CFR 10.115). The information sheet guidance represents the agency's current thinking on completing the Form FDA 1572. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information for Form FDA 1572 have been approved under OMB Control No. 0910–0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/Guidance7ComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: May 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13420 Filed 6–3–10; 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; Cell Death in Neurodegeneration.

Date: June 11, 2010.

Time: 9 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, 1250 22nd Street, NW., Washington, DC 20037.

Contact Person: Seetha Bhagavan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, bhagavas@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: May 27, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–13412 Filed 6–3–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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: National Institute of Child Health and Human Development Special Emphasis Panel, Pediatric Trials Network.

Date: June 23, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sathasiva B. Kandasamy, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304. (301) 435–6680. skandasa@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 26, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–13482 Filed 6–3–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research; Amended Notice of Meeting

ACTION: Notice of cancellation of consideration of a proposed action