

ANCC/PSNA Provider Reference Number: 205-3-A-09.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to "SoCRA". Mail to: SoCRA (see *Contact* for address). To register via the Internet, go to http://www.socra.org/html/FDA_Conference.htm. (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the public workshop, contact SoCRA (see *Contact*).

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting—Science, Regulation, Error, and Safety; (3) Part 11 Compliance—Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings With FDA: Why, When, and How; (9) Investigator Initiated Research; (10) Medical Device Aspects of Clinical Research; (11) Working With FDA's Center for Biologics Evaluation and Research; and (12) The Inspection Is Over—What Happens Next? Possible FDA Compliance Actions.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of

1996 (Public Law 104-121) as outreach activities by Government Agencies to small businesses.

Dated: December 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-32435 Filed 12-19-11; 8:45 am]

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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 RFA Panel: Challenge on the Transition from Acute to Chronic Neuropathic Pain

Date: January 9-10, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: John Bishop, Ph.D., Scientific Review Officer Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408-9664, bishopj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Topics in Infectious Diseases and Microbiology

Date: January 12, 2012.

Time: 1 p.m. to 3 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: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, (301) 996-5819, zhengli@csr.nih.gov.

(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: December 13, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-32520 Filed 12-19-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Published Privacy Impact Assessments on the Web

AGENCY: Privacy Office, DHS.

ACTION: Notice of Publication of Privacy Impact Assessments (PIA).

SUMMARY: The Privacy Office of DHS is making available seven PIAs on various programs and systems in DHS. These assessments were approved and published on the Privacy Office's web site between September 1, 2011 and November 30, 2011.

DATES: The PIAs will be available on the DHS Web site until February 21, 2012, after which they may be obtained by contacting the DHS Privacy Office (contact information below).

FOR FURTHER INFORMATION CONTACT:

Mary Ellen Callahan, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528, or email: pia@hq.dhs.gov.

SUPPLEMENTARY INFORMATION: Between September 1, 2011 and November 30, 2011, the Chief Privacy Officer of the DHS approved and published seven Privacy Impact Assessments (PIAs) on the DHS Privacy Office web site, www.dhs.gov/privacy, under the link for "Privacy Impact Assessments." These PIAs cover seven separate DHS programs. Below is a short summary of those programs, indicating the DHS component responsible for the system, and the date on which the PIA was approved. Additional information can be found on the web site or by contacting the Privacy Office.

System: DHS/FEMA/PIA-018 Suspicious Activity Reporting (SAR).

Component: Federal Emergency Management Agency (FEMA).

Date of approval: September 9, 2011.

FEMA, a component of DHS, manages a process for SAR. This process, assigned to FEMA's Office of the Chief Security Officer, is designed to collect, investigate, analyze, and report suspicious activities to the Federal Bureau of Investigation's (FBI) Joint

Terrorism Task Force, Federal Protective Service, and/or other federal, state, or local law enforcement authorities required to investigate and respond to terrorist threats or hazards to homeland security. FEMA is conducted this PIA because this SAR process collects, maintains, and uses PII.

System: DHS/NPPD/US-VISIT/PIA-007(a) Biometric Interoperability Between the U.S. Department of Homeland Security and the U.S. Department of Justice.

Component: National Protection and Programs Directorate (NPPD) and United States Visitor and Immigrant Status Indicator Technology (US-VISIT).

Date of approval: September 16, 2011.

In 2006, the US-VISIT Program of DHS and the Criminal Justice Information Services Division of the FBI, Department of Justice (DOJ), developed an interoperability project to support the sharing of information among DHS, DOJ, and their respective stakeholders. This PIA update was conducted to reflect the expansion of DHS-DOJ interoperability to include new users and uses not covered. In addition, this PIA allows users to access more data in IDENT.

System: DHS/ICE/PIA-031 Alien Medical Tracking Systems.

Component: Immigration and Customs Enforcement (ICE).

Date of approval: September 26, 2011.

ICE provides medical care to and maintains medical records about aliens that ICE detains for violations of U.S. immigration law. The ICE Health Service Corps, a division of ICE's Office of Enforcement and Removal Operations, has several information technology systems that are used to track information from medical records for aliens in ICE custody for various monitoring and reporting purposes. These are the Social Services Database, Hospitalization Database, Significant Detainee Illness Spreadsheet, Mental Health Coordination Database, Epidemiology Database, and Performance Improvement Database. This PIA describes the data maintained in these medical tracking systems, the purposes for which this information is collected and used, and the safeguards ICE has implemented to mitigate privacy and security risks to PII stored in these systems.

System: DHS/ICE/PIA-004(a) ICE Pattern Analysis and Information Collection (ICEPIC) Update.

Component: ICE.

Date of approval: October 26, 2011.

ICE has established a system called the ICEPIC system. ICEPIC is a toolset

that assists ICE law enforcement agents and analysts in identifying suspect identities and discovering possible non-obvious relationships among individuals and organizations that are indicative of violations of the customs and immigration laws as well as possible terrorist threats and plots. The PIA for ICEPIC was published in January 2008. This PIA Update was completed to provide transparency related to the Law Enforcement Information Sharing Service that enables law enforcement agencies outside DHS to query certain information available through ICEPIC. Additionally, through LEIS DHS law enforcement personnel are able to query external law enforcement agencies' sensitive but unclassified law enforcement information.

System: DHS/ICE/PIA-015(c) Enforcement Integrated Database Update.

Component: ICE.

Date of approval: November 7, 2011.

The Enforcement Integrated Database (EID) is a DHS shared common database repository for several DHS law enforcement and homeland security applications. EID captures and maintains information related to the investigation, arrest, booking, detention, and removal of persons encountered during immigration and criminal law enforcement investigations and operations conducted by ICE, U.S. Customs and Border Protection, and U.S. Citizenship and Immigration Services, all components within DHS. The PIA for EID was published in January 2010. In July 2010, a PIA Update for EID was published to address an expansion of the information entered into EID and the scope of external information sharing. This EID PIA Update addresses planned changes to the types of information shared and an added method of sharing.

System: DHS/S&T/PIA-006 Protected Repository for the Defense of Infrastructure Against Cyber Threats (PREDICT).

Component: Science and Technology.

Date of approval: November 8, 2011.

The S&T Directorate's PREDICT system has undergone a PIA 3-Year Review. The PIA requires no changes and continues to accurately relate to its stated mission. PREDICT is a repository of test datasets of Internet traffic data that is made available to approved researchers and managed by an outside contractor serving as the PREDICT Coordination Center. The goal of PREDICT is to create a national research and development resource to bridge the gap between (a) the producers of

security-relevant network operations data and (b) technology developers and evaluators who can use this data to accelerate the design, production, and evaluation of next-generation cyber security solutions, including commercial products.

System: DHS/ALL/PIA-013(a) PRISM System Update.

Component: DHS.

Date of approval: November 10, 2011.

DHS Management Directorate, Office of the Chief Procurement Officer is the owner of the PRISM contract writing management system. PRISM provides comprehensive, Federal Acquisition Regulation-based acquisition support for all DHS headquarters entities. The purpose of this PIA update is to reflect changes to the collection of information, and the addition of a classified PRISM system.

Dated: December 12, 2011.

Mary Ellen Callahan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2011-32483 Filed 12-19-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2011-0040; OMB No. 1660-0045]

Agency Information Collection Activities: Proposed Collection; Comment Request; Inspection of Insured Structures by Communities

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed extension, without change, of a currently approved collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning extension of the Inspection of Insured Structures by Communities. The community inspection report requires that FEMA consult with local officials and others in Monroe County, Village of Islamorada, and the City of Marathon following any hurricane that may hit the Florida Keys, concerning compliance of insured buildings with the community's floodplain management ordinance.