

FOIA REVIEW OF THE CCR DATA FIELDS—Continued

Data field	Exempt status	Public comments
(18) Lessor Phone .....	Exempt—5 U.S.C. 552(b)(6).	
(19) Lessor Fax .....	Exempt—5 U.S.C. 552(b)(6).	
(20) Lessor Email .....	Exempt—5 U.S.C. 552(b)(6).	
(21) Name of Person Signing Lease .....	Not exempt under the FOIA.	
(22) Name of Person Witnessing Lease Signature.	Not exempt under the FOIA.	
(23) Payee Name .....	Exempt—5 U.S.C. 552(b)(4).	
(24) Payee Address (including City, State, and Postal Code).	Exempt—5 U.S.C. 552(b)(4).	
(25) Payee Phone .....	Exempt—5 U.S.C. 552(b)(4).	
(26) Payee Fax .....	Exempt—5 U.S.C. 552(b)(4).	
(27) Payee Email .....	Exempt—5 U.S.C. 552(b)(4).	
(28) Unit Price Schedule (Including Itemized Construction Costs for Tenant Buildout Items Such as Drywall Partitioning, Electrical Outlets, Doors, Carpeting, Locks, and Cabinets).	Exempt—5 U.S.C. 522(b)(4).	
(29) HVAC Overtime Rate .....	Not exempt under the FOIA.	
(30) Corporate Resolution .....	Exempt—5 U.S.C. 552(b)(4).	
(31) Partnership Agreement .....	Exempt—5 U.S.C. 552(b)(4).	
(32) Adjustment for Vacant Premises Rate .....	Not exempt under the FOIA.	
(33) Legal Description of Building .....	Not exempt under the FOIA.	
(34) Normal Business Hours of Building .....	Not exempt under the FOIA.	
(35) Agency Name .....	Exempt—5 U.S.C. 552(b)(5) and (7).	
(36) Floor Plan .....	Exempt—5 U.S.C. 552(b)(5) and (7).	
(37) Identification of Building Floors Occupied ..	Not exempt under the FOIA.	
(38) Tax Payer Identification Number .....	Exempt—5 U.S.C. 552(b)(6).	
(39) Social Security Number .....	Exempt—5 U.S.C. 552(b)(6).	
(40) DUNS Number .....	Not exempt under the FOIA.	
(41) DUNS+4 .....	Exempt—5 U.S.C. 552(b)(4).	
(42) Financial Institution .....	Exempt—5 U.S.C. 552(b)(4).	
(43) Account Number .....	Exempt—5 U.S.C. 552(b)(4).	
(44) ABA Routing ID .....	Exempt—5 U.S.C. 552(b)(4).	
(45) Automated Clearing House (ACH) Network U.S. Phone.	Exempt—5 U.S.C. 552(b)(4).	
(46) ACH Non-U.S. Phone .....	Exempt—5 U.S.C. 552(b)(4).	
(47) ACH Fax .....	Exempt—5 U.S.C. 552(b)(4).	
(48) ACH E-Mail .....	Exempt—5 U.S.C. 552(b)(4).	

Dated: July 20, 2012.

**John D. Thomas,**

*Director, Center for Lease Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier OS-0990-0269]

**Agency Information Collection Request. 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons

are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, OMB number, and OS document identifier, to [Sherrette.funncoleman@hhs.gov](mailto:Sherrette.funncoleman@hhs.gov), or call the Reports Clearance Office on (202) 690-6162. Written comments and

recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60-days.

*Proposed Project:* Complaint Forms for Discrimination; Health Information Privacy Complaints OMB No. 0990-0269—Extension—Office of Civil Rights.

*Abstract:* The Office for Civil Rights is seeking an extension on an approval for a 3-year clearance on a previous collection. Individuals may file written complaints with the Office for Civil Rights when they believe they have been discriminated against by programs or entities that receive Federal financial assistance from the Health and Human Service or if they believe that their right to the privacy of protected health information has been violated. Annual Number of Respondents: frequency of submission is for record keeping and reporting on occasion.

## ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Civil Rights Complaint Form .....	Individuals or households, Not-for-profit institutions.	3493	1	45/60	2620
Health Information Privacy Complaint Form.	Individuals or households, Not-for-profit institutions.	10,286	1	45/60	7715
Total .....	.....	.....	.....	.....	10,335

**Keith A. Tucker,**

*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### International Workshop on Alternative Methods for *Leptospira* Vaccine Potency Testing: State of the Science and the Way Forward

**AGENCY:** Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

**ACTION:** Announcement of a Workshop; Call for Abstract Submissions.

**SUMMARY:** The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces an "International Workshop on Alternative Methods for *Leptospira* Vaccine Potency Testing: State of the Science and the Way Forward." This workshop, the second in a series of specialized vaccine workshops, will review recent advances and innovations in science and technology that can be applied to *Leptospira* vaccine potency testing. The goal is to promote development of innovative testing methods and approaches that may provide improved accuracy, efficiency, and worker safety and that are more humane and use fewer or no animals. The workshop will also address global acceptance and implementation of scientifically valid alternative methods.

The workshop is open to the public at no charge with attendance limited only by the available space; however, advance registration is required (see **DATES**). NICEATM also invites submission of abstracts for scientific posters for display at the workshop (see **SUPPLEMENTARY INFORMATION**).

**DATES:** The workshop is scheduled for September 19–21, 2012. Sessions will begin at 1:00 p.m. CDT on September 19 and 8:00 a.m. on September 20 and 21.

Sessions will end at approximately 6:00 p.m. on September 19 and 20 and at 1:00 p.m. on September 21. The deadline for registration is September 7, 2012. Due to U.S. Department of Agriculture (USDA) security requirements, onsite registration at the workshop will not be available. The deadline for submission of poster abstracts is August 13, 2012.

**ADDRESSES:** The workshop will be held at the USDA Center for Veterinary Biologics at the National Centers for Animal Health, 1920 Dayton Avenue Ames, Iowa 50010. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Debbie McCarley at voice telephone: 919-541-2384 or email: [mccarley@niehs.nih.gov](mailto:mccarley@niehs.nih.gov). TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least 5 business days in advance of the event.

**FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2-16, Research Triangle Park, NC, 27709, (telephone) 919-541-2384, (fax) 919-541-0947, (email) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive Morrisville, NC 27560.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

Leptospirosis is an emerging and widespread bacterial zoonotic disease caused by spirochetes of the genus *Leptospira*. An estimated 500,000 human cases of leptospirosis occur worldwide each year, with a fatality rate of up to 25% in some regions. Designated a Neglected Tropical Disease by the NIH and a Neglected Zoonotic Disease by the World Health Organization, leptospirosis is a global research and public health priority.

Leptospirosis affects numerous animal species including livestock, pets, and wildlife. Vaccines have been developed for most susceptible livestock and domestic pet species and are widely used in the U.S. and other countries. Human *Leptospira* vaccines that protect

against region-specific serovars are also available for workers in high-risk professions in selected countries, although none are currently approved for use in the United States.

Regulatory authorities require potency testing prior to release of each production lot of *Leptospira* vaccine to ensure that it will be effective. However, the current testing methods require the use of large numbers of laboratory animals that experience significant unrelieved pain and distress, accounting for over one-third of the animals reported to the USDA in this pain category. A recent international workshop, organized by NICEATM, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and their international partners, identified *Leptospira* vaccines as one of the three highest priorities for future research, development, and validation of alternative test methods that could further reduce, refine (enhance animal well-being and lessen or avoid pain and distress), or replace animal use for vaccine potency testing (Stokes et al., 2011). The USDA has developed and validated *in vitro* enzyme-linked immunosorbent assay (ELISA) antigen quantification methods for potency determination of vaccines for several *Leptospira* serovars (i.e., *Leptospira interrogans* serovars *pomona*, *canicola*, *icterohaemorrhagiae*, and *Leptospira kirschneri* serovar *grippotyphosa* [Kulpa-Eddy, 2012; USDA, 2009a, 2009b, 2009c, 2011]).

This workshop, the second in a series of specialized vaccine workshops, will review recent advances and innovations in science and technology that can be applied to the development of new methods and approaches for *Leptospira* vaccine potency testing. These new methods and approaches may provide improved accuracy, efficiency, and worker safety, and would be more humane and use fewer or no animals. Participants will develop a strategy to achieve global acceptance and implementation of scientifically valid alternative methods.