FRTIB–10

SYSTEM NAME:

Identity Management System (IDMS).

SYSTEM LOCATION:

[CHANGE TO READ]

Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002. Some data covered by this system may be at Federal buildings and Federally-leased space where staffed guard-stations have been established in facilities that have installed the Personal Identity Verification (PIV) system, as well as the physical security offices or computer security offices of those locations.

SYSTEM MANAGER(S) AND ADDRESS:

[CHANGE TO READ]

The Chief Financial Officer maintains the Agency's electronic identity data and all other records in FRTIB–10. The Chief Financial Officer may be contacted in writing at 77 K Street NE., Suite 1000, Washington, DC 20002.

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Individuals seeking to determine whether this system of records contains information about themselves should send inquiries to the Chief Financial Officer at Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002. When requesting notification of or access to records covered by FRTIB–10, an individual should provide his/her full name, date of birth, social security number, and home address in order to establish identity.

* * * * *

FRTIB–11

SYSTEM NAME:

Financial Disclosure Reports and Outside Business Interest Records.

SYSTEM LOCATION:

[CHANGE TO READ]

Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002.

SYSTEM MANAGER(S) AND ADDRESS:

[CHANGE TO READ]

Ethics Officer, Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002.

* * * * *

FRTIB–12

SYSTEM NAME:

Collection Records.

SYSTEM LOCATION:

[CHANGE TO READ]

Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002.

SYSTEM MANAGER(S) AND ADDRESS:

[CHANGE TO READ]

Associate General Counsel, Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002.

NOTIFICATION PROCEDURE:

[CHANGE TO READ]

Inquiries under the Privacy Act of 1974 should be addressed to the Privacy Act Officer, Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002. All individuals making inquiries should provide with their requests as much descriptive matter as is possible to identify the particular record desired. The System Manager will advise as to whether the Board or FMS will process the record request.

* * * * *

FRTIB–13

SYSTEM NAME:

Fraud and Forgery Records.

SYSTEM LOCATION:

[CHANGE TO READ]

These records are located at the Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002 and at the office of the entity engaged by the Agency to perform record keeping services for the TSP. The current address for the Agency's record keeper is listed at *http://www.tsp.gov.*

SYSTEM MANAGER(S) AND ADDRESS:

[CHANGE TO READ]

Director, Office of Participant Services, Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002.

NOTIFICATION PROCEDURE:

Inquiries under the Privacy Act of 1974 should be addressed to the Privacy Act Officer, Federal Retirement Thrift Investment Board, 77 K Street NE., Suite 1000, Washington, DC 20002. All individuals making inquiries should provide with their requests as much descriptive matter as is possible to identify the particular record desired.

[FR Doc. 2012–4489 Filed 2–24–12; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Recommendations on the Use of the Murine Local Lymph Node Assay for Potency Categorization of Chemicals Causing Allergic Contact Dermatitis: Availability of Federal Agency Responses

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

ACTION: Availability of Agency Responses.

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of U.S. Federal agency responses to ICCVAM test method recommendations on the use of the murine local lymph node assay (LLNA) for potency categorization of chemicals causing allergic contact dermatitis (ACD). ICCVAM forwarded the recommendations to Federal agencies and made these recommendations available to the public (76 FR 45254). In accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3), agencies have notified ICCVAM in writing of their findings, and ICCVAM is making these responses available to the public. Federal agency responses are available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/methods/immunotox/LLNApotency.htm.* The ICCVAM recommendations are provided in the ICCVAM test method evaluation report (ICCVAM, 2011).

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.* Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

The LLNA is accepted worldwide as a valid alternative to traditionally accepted guinea pig test methods for assessing ACD hazard potential for most testing applications. In January 2007, the U.S. Consumer Product Safety Commission (CPSC) requested that NICEATM and ICCVAM evaluate the LLNA for its usefulness for determining skin sensitization potency categories.

The CPSC, under the Federal Hazardous Substances Act, requires hazard labeling of products considered to be strong skin sensitizers. Results from tests that could be used to identify potential strong human skin sensitizers would support the CPSC and other agencies with an interest in identifying strong skin sensitizers. While guinea pig tests have traditionally been used to categorize the potency of skin sensitizers, the LLNA uses fewer animals, requires less time to perform, provides dose-response information, and eliminates the pain and distress produced by positive reactions.

Accordingly, NICEATM and ICCVAM evaluated the extent that the LLNA could be used to correctly predict ''strong'' versus ''other than strong'' human skin sensitizers. NICEATM, working in collaboration with the ICCVAM Interagency Immunotoxicity Working Group (IWG), prepared a draft background review document (BRD) and draft recommendations for use of the LLNA for potency categorization of chemicals that cause ACD in humans. The draft BRD and draft ICCVAM recommendations were reviewed in a public meeting of an international independent scientific peer review panel in March 2008; the peer review panel report was made available to the public for comment in May 2008 (73 FR 29136). The Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) discussed and commented on the report, draft BRD, and draft ICCVAM recommendations at its June 2008 meeting (73 FR 25754). ICCVAM considered the panel's report, comments from SACATM, and public comments, and finalized its recommendations.

The final ICCVAM recommendations are provided in the *ICCVAM Test Method Evaluation Report: Usefulness and Limitations of the Murine Local Lymph Node Assay for Potency Categorization of Chemicals Causing Allergic Contact Dermatitis in Humans* (NIH Publication No. 11–7709, available at *http://iccvam.niehs.nih.gov/methods/immunotox/LLNA-pot/TMER.htm*). The test method evaluation report also includes an updated ICCVAM-recommended LLNA protocol and recommended future studies that may further characterize the usefulness and limitations of the LLNA for potency determinations. The final BRD, including additional analyses performed by NICEATM as recommended by the peer review panel, is included as an appendix to the test method evaluation report. ICCVAM recommended that positive results from ACD safety testing using the murine LLNA could be used to categorize some chemicals and products as strong skin sensitizers. However, since the current LLNA decision criterion only identified 52% of the strong human skin sensitizers, ICCVAM recommended that this criterion should not be used as the basis for determining that a substance is not a strong skin sensitizer. Therefore, the potency criterion should only be used in a screening approach, where chemicals that meet the criterion could be categorized as strong skin sensitizers, but chemicals that do not meet the criterion would require additional testing or information to determine that they are not strong skin sensitizers. In accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals and Animal Welfare Act regulations, the LLNA should be routinely considered when planning animal studies to evaluate whether chemicals and products are strong sensitizers in order to minimize animal use and to avoid unrelieved pain and distress, and should be used when determined appropriate.

Agency Responses to ICCVAM Recommendations

In June 2011, ICCVAM forwarded final test method recommendations on using the LLNA for potency categorization of chemicals to U.S. Federal agencies for consideration (76 FR 45254), in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3). The ICCVAM Authorization Act requires member agencies to review ICCVAM test method recommendations and notify ICCVAM in writing of their findings no later than 180 days after receipt of recommendations. The Act also requires ICCVAM to make ICCVAM recommendations and agency responses available to the public. Agency responses are to include identification of relevant test methods for which the ICCVAM test method recommendations may be added or substituted and indicate any revisions or planned revisions to existing guidelines, guidances, or regulations to be made in response to these recommendations. Complete agency responses are available at *http://iccvam.niehs.nih.gov/methods/immunotox/LLNApotency.htm.*

Background Information on NICEATM, ICCVAM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products while reducing animal use, refining animal use by enhancing animal welfare and lessening or avoiding unrelieved pain and distress, or replacing animals used for testing. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*).

SACATM was established in response to the ICCVAM Authorization Act [Section 285*l*–3(d)] and is composed of scientists from the public and private sectors (67 FR 11358). SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167.*

Reference

ICCVAM. 2011. ICCVAM Test Method Evaluation Report: Usefulness and Limitations of the Murine Local Lymph Node Assay for Potency Categorization of Chemicals Causing Allergic Contact Dermatitis in Humans. NIH Publication No. 11–7709. Research Triangle Park, NC: National Institute of Environmental Health Sciences. Available: *http://iccvam.niehs.nih.gov/methods/immunotox/LLNA-pot/TMER.htm.*

Dated: February 15, 2012.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2012–4541 Filed 2–24–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Michael W. Miller, Ph.D., State University of New York, Upstate Medical University: Based on the report of an investigation conducted by the State University of New York, Upstate Medical University (SUNY UMU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Michael W. Miller, former Professor and Chair, Department of Neuroscience and Physiology, SUNY UMU, engaged in research misconduct in research supported by National Institute of Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH), grants R01 AA07568–18A1, R01 AA06916, and P50 AA017823–01.

ORI finds that the Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in grant applications R01 AA07568–18, R01 AA07568–18A1, R01 AA006916–25, and P50 AA017823–01 and in the following:

- Miller, M.W., Hu, H. ''Lability of neuronal lineage decisions is revealed by acute exposures to ethanol.'' *Dev. Neurosci.* 31(1–2):50–7, 2009 (''*Dev. Neurosci.* 2009'')
- Bruns, M.B., Miller, M.W. ''Functional nerve growth factor and trkA autocrine/paracrine circuits in adult rat cortex are revealed by episodic ethanol exposure and withdrawal.'' *J. Neurochem.* 100(5):1115–68, 2007 (''*J. Neurochem.* 2007'')
- A prepared manuscript submitted to *PNAS* for publication.

As a result of its investigation, SUNY UMU recommended that *Dev. Neurosci.* 2009 and *J. Neurochem.* 2007 be retracted. Both publications have now been retracted:

- *Dev. Neurosci.* 2009 was retracted online on January 19, 2012, at: *http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowPDF&ArtikelNr=323471&Ausgabe=0&ProduktNr=224107&filename=323471.pdf.*
- *J. Neurochem.* 2007 was retracted online on January 23, 2012, at: *http://onlinelibrary.wiley.com/doi/10.1111/j.1471-4159.2012.07662.x/full.*

Specifically, ORI finds that the Respondent:

- Falsified Figure 5 in NIH grant application R01 AA07568–18A1 by altering the bar graphs to make the experimental results appear valid and consistent with his hypothesis that ethanol exposure *in-utero* alters the transition of cells from Pax 6 expression to Tbr2 expression, which is critical to normal brain development. Specifically:

a. In the VZ/SZ panel (upper row, right), Dr. Miller decreased the values by 50% for the bar graphs representing control and treated mice for ''Tbr2,'' ''both,'' and ''both/Ki-67,'' to falsely report an equivalent frequency of Tbr2 expressing cells in the right and left panels; this result was required for the experiment to appear valid;

b. In the MGE panel (lower row, right), Dr. Miller altered the bar graphs representing control and treated mice for ''Ki-67,'' ''Pax6,'' and ''both'' to falsely report that ethanol increased the frequency of K–67+ cells and to report an equivalent frequency of Pax expressing cells in the right and left panels.

- Fabricated bar graphs in Supplemental Figure 2 in a manuscript submitted to *PNAS* and text in the manuscript also appearing in the grant application AA00616–25 to support the hypothesis that ethanol exposure during postnatal weeks 1 and 2 causes specific neuronal cell death in layers II/III and V of the cortex. Specifically, Dr. Miller:

a. Fabricated bar graphs in Supplemental Figure 2 and related text in the *PNAS* manuscript to show that in select layers of the cortex, ethanol induced neuronal death occurred in post-natal day 10 (P10) mice;

b. Included fabricated text in the *PNAS* manuscript and the grant application citing results of experiments using 15–25-day-old mice treated with ethanol during the second postnatal week, when these mice were never generated.

- Falsified Figure 6 in a manuscript submitted to *PNAS* by altering data points for the labeling index of caspase3 and TUNEL in cortex layers II/III and V after exposure to ethanol in postnatal day 7 (P7) mice, such that the two assays confirmed each other. The same data were also included as Figure 4 in NIH grant application R01 AA06916 and as Figure 7 in a poster presentation at the 2009 Research Society on Alcoholism.
- Falsified the figure legends and/or text in a published paper and multiple grant applications to support the primary hypothesis of the published paper that gestational alcohol exposure had an effect on brain development by affecting the way neurons differentiate and migrate into the cortex, rather than by changes to cell growth or death. Specifically, Dr. Miller falsely reported the number of animals (n) that were used in figure legends and/or text in the following:
  - Figures 2 and 5, *Dev. Neurosci.* 2009, also included as Figures 3 and 4, respectively, in R01 AA07568–18;
  - Figure 4 and Table 2 in P50 AA017823–01.
- Falsified Figures 4 and 6 in *J. Neurochem.* 2007 by altering bar graphs to increase the significance of the effect of ethanol exposure and/or withdrawal on NGF or trkA protein expression, thereby conforming with the paper's hypothesis that ethanol exposure and withdrawal affect the normal NGF/trkA circuits in cortical layer V. Specifically, Dr. Miller:

a. Increased the value of the ethanol treated NGF expression in Figure 4 and decreased the value of withdrawal NFG to alter the difference between the two from approximately 2.2% to 11.6%, thereby falsely reporting significance where there was none;

b. In Figure 6:

(a) Increased the value of withdrawal trkA data by approximately 70% to falsely report significance with relation to the ethanol treated value and increase significance with relation to the control;

(b) Increased the value of the ethanol treated phospho-trkA data by approximately 100% to increase the significance with relation to the control;

(c) Falsely reported the results for Figure 6 as showing a nearly doubled ratio of p-trkA to total trkA after ethanol exposure when there was no increase at all.

Dr. Miller has entered into a Voluntary Exclusion Agreement (Agreement). Dr. Miller neither admits nor denies committing research misconduct but accepts ORI has found evidence of research misconduct as set forth above.

Dr. Miller has voluntarily agreed:

(1) To exclude himself voluntarily from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as ''covered transactions'' pursuant to HHS' Implementation (2 CFR part 376 *et seq*) of OMB Guidelines to Agencies on Governmentwide Debarment and