

U19 AI056542, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant U19 DK57958, and NIH/Novartis Cooperative Research and Development Agreement 96-MH-01/NIHITC-0697.

PHS found that Respondent engaged in scientific misconduct by falsifying in seven publications reports of research results in NIH-supported experiments with non-human primate (NHP) renal allograft recipients.

Specifically, PHS found that Respondent engaged in scientific misconduct by falsely reporting in five publications¹ that at least 32 specific non-human primates in a renal allograft transplantation study had received bilateral nephrectomies, while in fact an intrinsic kidney was left in place in each animal, and generally, in two additional publications² by reporting that all long term surviving non-human primate renal allograft recipients had

¹ Hutchings, A., Wu, J., Asiedu, C., Hubbard, W., Eckhoff, D., Contreras, J., Thomas, F.T., Neville, D., & Thomas, J.M. "The immune decision toward allograft tolerance in non-human primates requires early inhibition of innate immunity and induction of immune regulation." *Transpl Immunol.* 11(3-4):335-344, July-September 2003. (Retraction required by UAB.)

Thomas, J.M., Eckhoff, D.E., Contreras, J.L., Lobashevsky, A.L., Hubbard, W.J., Moore, J.K., Cook, W.J., Thomas, F.T., & Neville, D.M. Jr. "Durable donor-specific T and B cell tolerance in rhesus macaques induced with peritransplantation anti-CD3 immunotoxin and deoxyspergualin: Absence of chronic allograft nephropathy." *Transplantation* 69(12):2497-2503, June 27, 2000. (Retracted.)

Thomas, J.M., Contreras, J.L., Jiang, X.L., Eckhoff, D.E., Wang, P.X., Hubbard, W.J., Lobashevsky, A.L., Wang, W., Asiedu, C., Stavrou, S., Cook, W.J., Robbin, M.L., Thomas, F.T., & Neville, D.M. Jr. "Peritransplant tolerance induction in macaques: Early events reflecting the unique synergy between immunotoxin and deoxyspergualin." *Transplantation* 68(11):1660-1673, December 15, 1999. (Retracted.)

Contreras, J.L., Eckhoff, D.E., Cartner, S., Frenette, L., Thomas, F.T., Robbin, M.L., Neville, D.M. Jr., & Thomas, J.M. "Tolerability and side effects of anti-CD3-immunotoxin in preclinical testing in kidney and pancreatic islet transplant recipients." *Transplantation* 68(2):215-219, July 27, 1999. (Retracted.)

Contreras, J.L., Wang, P.X., Eckhoff, D.E., Lobashevsky, A.L., Asiedu, C., Frenette, L., Robbin, M.L., Hubbard, W.J., Cartner, S., Nadler, S., Cook, W.J., Sharff, J., Shiloach, J., Thomas, F.T., Neville, D.M. Jr., & Thomas, J.M. "Peritransplant tolerance induction with anti-CD3-immunotoxin: A matter of proinflammatory cytokine control." *Transplantation* 65(9):1159-1169, May 15, 1998. (Retracted.)

² Hubbard, W.J., Eckhoff, D., Contreras, J.L., Thomas, F.T., Hutchings, A., & Thomas, J.M. "STEALTH on the preclinical path to tolerance." *Graft* 5(6):322-330, 2002. (Retraction required by UAB—Journal has ceased publication.)

Hubbard, W.J., Contreras, J.V., Eckhoff, D.E., Thomas, F.T., Neville, D.M., & Thomas, J.M. "Immunotoxins and tolerance induction in primates." *Current Opinion in Organ Transplantation* 5:29-34, 2000. (Partially retracted.)

received bilateral nephrectomies of their native kidneys.

The objective of the research was to test the effectiveness of different immunomodulating agents, administered around the time of renal transplantation in non-human primates, in preventing rejection of the transplanted kidney. To determine whether or not the transplanted kidney was functioning (able to sustain life) after the immunomodulating therapy, the animals were to have both of their native kidneys removed at or shortly after the time of transplant, so that their survival would depend solely on the viability of the transplanted kidney. Failure to remove both native kidneys rendered it impossible to assess the effectiveness of the immunomodulating treatment.

Both Dr. Contreras and PHS are desirous of concluding this matter without further expense of time and other resources, and the parties have entered into a Voluntary Exclusion Agreement to settle the matter. Dr. Contreras accepted responsibility for the reporting described above, but denied that he intentionally committed scientific misconduct. The settlement is not an admission of liability on the part of the Respondent.

Dr. Contreras has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on June 17, 2009:

(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" and defined by 2 CFR Parts 180 and 376; and

(2) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Developmental Disabilities Program Independent Evaluation Project.

OMB No.: New Collection.

Description: The Developmental Disabilities Program Independent Evaluation (DDPIE) Project is an independent (non-biased) evaluation to examine through rigorous and comprehensive performance-based research procedures the targeted impact on the lives of people with developmental disabilities and their families of three programs funded under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act): (1) State Councils on Developmental Disabilities (SCDDs); (2) State Protection and Advocacy Systems for Individuals with developmental disabilities (P&As); and (3) University Centers for Excellence in Developmental Disabilities (UCEDDs). The intent of this evaluation is to understand and report on the accomplishments of these programs, including collaborative efforts among the DD Network programs. The results of this evaluation will provide a report to the Administration on Developmental Disabilities (ADD) (the agency that administers these programs) with information on the effectiveness of its programs and policies and serve as a way for ADD to promote accountability to the public.

The independent evaluation is a response to accountability requirements for ADD as identified in the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), the Government Performance and Results Act (GPRA) of 1993, and the Program Assessment Rating Tool (PART), administered by the Office of Management and Budget (OMB). This project meets the requirements of PART by providing a non-biased method of evaluating the effectiveness and impact of DD Network programs on the lives of people with developmental disabilities and their families.

ADD is seeking OMB approval for the evaluation tools (e.g., data collection instruments). The evaluation tools are designed to collect data for two purposes: (1) To measure the programs according to indicators (structural, process, output, and outcome) in key function areas; and (2) to establish performance standards for measuring

the impact of each of the programs. The evaluation tools are primarily protocols for conducting interviews with various staff of the three programs and stakeholders associated with the programs. The interview protocols were tested during a pilot study in 2008. There is also a self-administered form for each of the programs to be completed by Executive Directors or his/her designee. The self-administered form was developed as a result of the

pilot study and, therefore, has not been tested for reliability and validity. It is intended that the clearance process will be a mechanism for determining the reliability, validity, and feasibility of using this instrument.

Respondents: Staff of State Councils on Developmental Disabilities, State Protection and Advocacy Systems for Individuals with developmental disabilities, and University Centers for Excellence in Developmental

Disabilities, Education, Research, and Service; individuals with developmental disabilities; parents of individuals with developmental disabilities; siblings of individuals with developmental disabilities; guardians; advocates; policymakers; service providers; university faculty; and others (e.g., DDC chairs, members of Protection and Advocacy boards of directors or commissioners; Consumer Advisory Committee members)

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
DD Council: Executive Director Interview	20	1	4	80
DD Council: Interview with Council Chair/Council Members	60	1	0.75	45
DD Council: Group Interview with Policymakers, Collaborators, and Grantees	160	1	2	320
UCEDD: Telephone Interview with Current and Graduated Students	100	1	0.75	75
UCEDD: Interview with the Consumer Advisory Committee	60	1	0.75	45
UCEDD: Interview with Peer Researchers and Colleagues	100	1	0.75	75
UCEDD: Interview with Recipients of Community Services or Members of Organizations/Agencies that Are Trained To Provide Community Services	100	1	0.75	75
UCEDD: Self-administered Form	20	1	8	160
P&A: Executive Director Interview	20	1	4	80
P&A: Staff Interview	60	1	0.75	45
P&A: Board of Directors (Commissioners)—Chair and Members	60	1	0.75	45
P&A: Group Interview with Policymakers and Collaborators	160	1	2	320
P&A: Interview with Recipient of Community Education	100	1	0.75	75
P&A: Interview with Clients	100	1	0.75	75
P&A: Self-administered Form	20	1	8	160
UCEDD: Interview with Director	20	1	4	80
DD Council: Group Interview with Recipients of Self-Advocacy and Leadership Education and Training	100	1	0.75	75
DD Council: Group Interview with Recipients of Education and Training to Improve Community Capacity	100	1	0.75	75
DD Council: Self-administered Form	20	1	8	160
DD Council Estimate of Total Burden Hours for Activities to Support Administration of Proposed Information Collection Instruments	20	1	33.50	670
P&A Estimate of Total Burden Hours for Activities to Support Administration of Proposed Information Collection Instruments	20	1	33.50	670
UCEDD Estimate of Total Burden Hours for Activities to Support Administration of Proposed Information Collection Instruments	20	1	33.50	670

Estimated Total Annual Burden Hours: 4,075.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* infocollection@acf.hhs.gov.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect

if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202-395-7245, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: June 30, 2009.

Janean Chambers,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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,