

- The respondent falsified the text describing the results in Figure 20 (“Inhibition of c-fos luciferase activity in S49 T cells transiently transfected with pIRES2-Riib-EGFP and treated with 8-Cl-cAMP”) in application 1 R01 AI46526–01A2 (p. 27), by falsely reporting N = 4, P less than 0.002, when the experiment had been performed only one time at the time that the application was submitted.

PHS also concluded that the respondent further demonstrated a lack of present responsibility as a Principal Investigator by submitting NIH grant proposals with additional unsupported experimental results:

- The pedigree and data for the family reported in grant application 2 R01 AR39501–12 and for Family 1 in grant application 2 R01 AR39501–12A1 are incorrect and the data pertaining to this family that Dr. Kammer subsequently provided to WFU after the inquiry were not the data reported in the applications. Dr. Kammer stated that he did not recall who in his laboratory gave him this pedigree. ORI noted that the actual PKA data for the “proof-of-principle” family, while suggesting that low PKA values may be hereditary (the presence of low PKA–I values in three generations), do not support the claims of the fabricated and mixed up pedigree and data that show that low PKA–I values were associated with Systemic Lupus Erythematosus (SLE) (application 2R01 AR39501–12).

- In application, R01 AI39501–12A1, the following unsupported statement was also included: “In both normal and disease controls, all T cells express CD59+ and there is no significant difference in its cell surface expression on CD4+, CD45RA+, CD4+, CD45RO+, CD8+, CD45RA+, CD8+, CD45RO+ subsets (n=4 each control group; data not shown).” No data could be produced to support the information in the grant application about these control experiments.

Dr. Kammer has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed for a period of three (3) years, beginning on February 15, 2005:

(1) 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, and

(2) To exclude himself 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” as defined in the debarment regulations at 45 CFR part 76. This voluntary exclusion precludes the respondent from receiving Federal research, research training, or other research related funds from the Federal Government for three (3) years, but shall not apply to the respondent’s participation in a Federal health care program as defined in section 1128B(f) of the Social Security Act and shall not apply to Federal funds used solely for purposes of teaching or training medical students, residents, or fellows in clinical medical matters.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852; (301) 443–5330.

Chris B. Pascal,

Director, 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

Proposed Projects:

Title: Evaluation of the Early Head Start Enhanced Home Visiting Pilot Project.

OMB No.: New Collection.

Description: The Head Start Reauthorization Act of 1994 established a special initiative creating funding for services for families with infants and toddlers. In response, the Administration on Children, Youth and Families (ACYF) within the Administration for Children and Families (ACF) developed the Early Head Start program. Since its inception, Early Head Start has expanded to include more than 700 programs and 70,000 families enrolled nationwide. The program is designed to produce outcome in four domains: (1) Child development, (2) family development, (3) staff development and (4)

community development. The Head Start Bureau has given programs a mandate to support the quality of all settings where children receive care by providing high-quality services and supporting parents and child care providers in caring for their young children.

In keeping with this mandate, the Head Start Bureau recently funded 24 Early Head Start programs to participate in the Enhanced Home Visiting Pilot Project. The goal of the pilot project is to develop program models for supporting relatives and neighbors and who care for Early Head Start children in acquiring the knowledge, skills and resources they need to support children’s healthy development.

The Enhanced Home Visiting Pilot Project evaluation will collect and disseminate information about the program models and service delivery strategies developed by the pilot sites, as well as the characteristics and needs of participating children, families and caregivers. The evaluation will collect and analyze information from three main sources: (1) Interviews with staff and focus groups with parents and caregivers to be conducted during two rounds of visits to pilot programs (in spring 2005 and 2006), (2) a program recordkeeping system for tracking services to be maintained by the pilot sites and (3) observational assessments of the quality of the caregiving environment and the interactions between children and caregivers to be conducted in spring 2006. All data-collection instruments have been designed to minimize the burden on respondents by minimizing the time required to respond. Participation in the study is voluntary.

The results of the research will be used by the Head Start Bureau and ACF to identify and disseminate information about promising program models and service delivery strategies and lessons learned from the experiences of the pilot programs.

Respondent: Early Head Starts directors, coordinators, specialists and home visitors; staff from other community service providers; parents of Early Head Start children; and neighbor and relative caregivers of Early Head Start children.

Annual Burden Estimates

ESTIMATED RESPONSE BURDEN FOR RESPONDENTS FOR THE ENHANCED HOME VISITING PILOT EVALUATION

Instrument	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Annual burden (hours)
Site Visit Protocols (2005):				
Director Protocol	24	1	3.0	72.0
Coordinator/Specialist Protocol	24	1	1.5	36.0
Community Partner Protocol	24	1	1.5	36.0
Home Visitor Protocol	48	1	1.5	72.0
Parent Protocol	192	1	1.5	288.0
Caregiver Protocol	192	1	1.5	288.0
Case Review Protocol	48	1	3.0	144.0
Recordkeeping System (2005)	24	^a 27	^b 2.0	1,296.0
Total for 2005				2,232.00
Site Visit Protocols (2006):				
Director Telephone Protocol	24	1	1.0	24.0
Director Protocol	12	1	3.0	36.0
Coordinator/Specialist Protocol	12	1	1.5	18.0
Community Partner Protocol	12	1	1.5	18.0
Home Visitor Protocol	24	1	1.5	36.0
Parent Protocol	96	1	1.5	144.0
Case Review Protocol	24	1	3.0	72.0
Recordkeeping System (2006)	24	^a 27	^b 1.0	648.0
Caregiver Observations (2006)	96	1	2.5	240.0
Total for 2006				1,236.0
Total for 2005 and 2006				1,734.0

^a Average expected number of children to be enrolled in the pilot per site. Expected enrollment ranges from 7 to 60 across the 24 sites.

^b Based on an estimated burden of 10 minutes per child per month.

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: grjohnson@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, Attn: Desk Officer for ACF; e-mail address: Katherine_T_Astrich@omb.eop.gov.

Dated: March 4, 2005.

Robert Stargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, NIEHS.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6) title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Environmental Health Sciences, including consideration of personal qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly

unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIEHS.

Date: April 3-5, 2005.

Closed: April 3, 2005, 8 p.m. to 9:30 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: April 4, 2005, 8:30 a.m. to 5:15 p.m.

Agenda: An overview of the organization and conduct of research in the Epidemiology Branch.

Place: Building 101 Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: April 5, 2005, 8 a.m. to adjournment.

Agenda: To review and evaluate Epidemiology Branch.

Place: Building 101 Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Lutz Birnbaumer, Scientific Director, Division of Intramural Research, National Institute of Environmental Health Sciences, National Institutes of Health, MD A2-09, P.O. Box 12233, Research Triangle Park, NC 17709, 919/541-3205.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation-Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances-Basic Research and Education; 93.894, Resources and Manpower Development in