

Officer on (202) 690-6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Written comments should be received within 30 days of this notice.

Dated: June 19, 2001.

Kerry Weems,

Acting Deputy Assistant Secretary, Budget.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Kuie-Fu (Tom) Lin, D.V.M., Medical University of South Carolina (MUSC): Based on the report of an investigation conducted by MUSC and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Lin, a former graduate student, Department of Biochemistry and Molecular Biology at MUSC, engaged in scientific misconduct in research supported by the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL29397, "Regulation and Function of Renal Kallikrein," and R01 HL56686, "Gene Therapy in Experimental Hypertension and Renal Diseases."

Specifically, PHS finds that Dr. Lin engaged in scientific misconduct by:

A. Falsifying research on the expression and effect of the human atrial natriuretic peptide (ANP) gene in rats reported in *Hypertension* 26:847-853, 1995. Dr. Lin falsified data in the text on page 850 that described RT-PCR results shown in Figure 3 as obtained from multiple control and experimental rats, when only one rat was tested for each group.

B. Falsifying research on the expression and effect of the human adrenomedullin gene in rats reported in *Hypertension Research* 20:269-277, 1997. Dr. Lin falsified data in: (a) Figure 2 on page 272 by reusing Figure 2 of the *Hypertension* paper cited in "A" above, and falsely relabeling it as being a test of ADM levels in experimental rats; (b) Table 1 on page 273 by stating concentrations of human ADM in experimental rat tissues without accounting for the high levels of endogenous cross-reactive rat ADM; and (c) Table 1 on page 273 by claiming that the levels of human ADM seen in rat tissues were obtained from four animals when the values were actually obtained from four serial dilutions of one sample. The journal published an erratum at 22(3):229, 1999.

C. Falsifying research on the expression and effect of the human ANP gene in rats reported in *Human Gene Therapy* 9:1429-1438, 1998. Dr. Lin falsified data in: (a) Figure 3 on page 1431 by reusing Figure 2 of the *Hypertension* paper cited in "A" above, and falsely relabeling it as being based on the use of an adenovirus vector to deliver the ANP (gene rather than the use of "naked DNA" described in the earlier paper); (b) text on page 1433 that stated concentrations of human ANP in experimental rat tissues without accounting for the high levels of endogenous cross-reactive rat ANP; and (c) Table 2 by making an inappropriate calculation for the renal blood flow (RBF) of the "AdCMV-LacZ" group by altering data (from animals that should not have been included because their venous flow was greater than their arterial flow), to falsely produce an average RBF value that was significantly different from the group receiving the ANP vector.

All three of the questioned papers described gene therapy models in which the introduced gene lowered blood pressure in hypertensive or salt-sensitive rats. Dr. Lin's falsifications greatly enhanced the apparent expression and effects of the introduced ANP and ADM genes in the experimental rats.

Dr. Lin states that he made honest mistakes and deeply regrets his unintentional errors in data handling.

Dr. Lin has entered into a Voluntary Exclusion Agreement (Agreement) with PHS in which he has voluntarily agreed:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as

defined in 45 CFR part 76 (Debarment Regulations) for a period of three (3) years, beginning on June 12, 2001;

(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 for a period of three (3) years, beginning on June 12, 2001;

(3) within 30 days of the effective date of the Agreement to submit letters of correction or retraction to:

(A) *Hypertension* 26:847-853, 1995: Requesting correction of the statement on page 850 to indicate that results on RT-PCR of tissue extracts were obtained with only one control and one experimental rat, rather than the four animals for each group claimed in the paper;

(B) *Hypertension Research* 20:269-277, 1997: Requesting retraction of Table 1; the notice to the journal should state that the values for human ADM in Table 1 were incorrect because they did not account for the high level of endogenous ADM detected in control tissues by the RIA, and that only a single rat was tested rather than the four animals claimed; and

(C) *Human Gene Therapy* 9:1429-1438, 1998: Requesting retraction of Figure 2 and correction of Table 2 to indicate that the renal blood flow value for the "Ad.CMV-LacZ (4% NaCl)" rats was falsified. The notice to the journal should state that Figure 2 was falsified because it was in large part a duplicate of a previously published figure and was falsified both because logit values were deliberately altered and because the results were obtained from experimental rats that were treated differently from those described in the paper. This statement should also note that the first paragraph on page 1433 contained misleading concentrations of human ANP in experimental tissues because they failed to account for the high level of cross-reactive endogenous ANP observed by the RIA used in control tissues.

These correction and retraction requirements will remain on the ALERT System until Dr. Lin sends, and ORI receives, copies of these letters that are consistent with the above language.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443-5330.

Chris Pascal,

Director, Office of Research Integrity.

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