

and the Assistant Secretary for Health have taken final action in the following case:

Michael E. Ganz, M.D., Case Western Reserve University: Based on the report of an investigation conducted by Case Western Reserve University (CWRU Report) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Ganz, Associate Professor of Medicine, CWRU, engaged in scientific misconduct by falsification and fabrication of research in grant application R01 DK058674–01A2, “The role of protein kinase C and shuttling proteins in diabetic kidney disease,” submitted to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH).

Specifically, PHS found that Dr. Ganz engaged in scientific misconduct by:

(1) Falsifying Figure 16 in NIH grant application R01 DK058674–01A2 by claiming that photomicrographs of glomeruli were from a streptozotocin model of induced diabetes in rat, while the photomicrographs were actually from tissue of human or other primate origin;

(2) Falsifying Figure 16 of this NIH grant application by claiming that six photomicrographs all represented glomeruli from different animals, whereas they actually were from only three different glomeruli, with each glomerulus being shown in two images with different orientations and/or magnifications; and

(3) Falsifying and fabricating documents, purportedly showing the source of the falsified Figure 16 in the NIH grant application, which the Respondent provided to the CWRU inquiry committee.

The research was significant because it was designed to develop a therapy to prevent the progressive glomerular hypertrophy and matrix deposition that occur with the renal disease associated with diabetes in animals and humans.

Dr. Ganz has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of five (5) years, beginning on December 18, 2002:

(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 referred to as “covered transactions” as defined in 45 CFR part 76 (Debarment Regulations); 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, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Director, Office of Research Integrity.

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Page 19937, third column, section “G.4.a(7)(b) Travel”, first paragraph, correct the typographical error “NCPCP” to read “NCCCP.”

Page 19938, first column, section “G.4.b”, second paragraph, after the phrase “For each proposal, the following information should be submitted:” insert the phrase “An Executive Summary consisting of a brief summary of proposed project, including goals, objectives, and description of who will complete the work.”

Page 19938, second column, section “G.5.a”, delete the phrase “(1 of 2)” from the header. Delete the first sentence “In addition to the general guidance provided in Section J-Other Requirements, the first two required progress reports should include a description of:” and replace it with “In addition to the guidance provided in Section J-Progress Reports 1 and 2 should include a description of:”

Page 19939, second column, section “G.6.a.(3)(f)”, delete this entire section.

Page 19939, second column, section “H.2. Availability of Funds”, delete all specific dollar amounts listed. New dollar amounts will be published in the annual open season announcement.

Page 19939, third column, section “H.2.b.(1)”, reads “Not less than 60 percent of cooperative agreement funds must be spent for screening, tracking, follow-up* * ***” Delete the term “tracking” and replace it with “case management.”

Page 19940, third column, section “H.4.Content”, second paragraph, delete “* * * 65 double spaced pages * * *” and replace it with “* * * 53 double spaced pages * * *”

Page 19941, second column, section “H.4.a.(4)(f) Overall measures of success/effectiveness”, second paragraph, delete “* * * fiscal year 2002–2003 * * *” and replace with “* * * proposed project year * * *”

Page 19941, third column, section “H.4.a.(5)(a) Travel”, insert the following requirements:

H.4.a.(5)(a)[5] Up to two staff members to participate in the NCCDPHP Annual Chronic Disease Conference (4 days).

H.4.a.(5)(a)[6] On alternating years, starting with 2003, up to two staff members to participate in the National Cancer Conference in Atlanta (5 days).

Page 19943, third column, section “I.1. Eligible Applicants”, third paragraph, add the following sentences: “However, after five consecutive years of NPCR funding as planning, applicants are expected to have achieved progress toward the Enhancement level of operations. If applicants have not been able to achieve

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02060]

National Cancer Prevention and Control Program Notice of Availability of Funds; Amendment 2

A notice announcing the availability of fiscal year (FY) 2002 funds for cooperative agreements for the National Cancer Prevention and Control Program (NCPCP) was published in the **Federal Register** April 23, 2002, Volume 67, Number 78, pages 19932–19950. The notice is amended as follows:

Delete Sections A. through F., page 19932, first column, through page 19934, second column. The information provided in these sections will be replaced in an open season announcement that will be published annually.

Page 19934, first and second column, section “G.2 Availability of Funds”, delete all specific dollar amounts listed. New dollar amounts will be published in the annual open season announcement.

Page 19935, first column, section “G.2.d Funding Preference”, delete the phrase “There are no funding preferences applicable to this component” and replace it with the phrase “Funding preference may be given to applicants from the prior year’s applications who were considered Approved but Unfunded (ABU). Those applicants will be named in the annual open season announcement.”

Page 19937, first column, section “G.4.a.(3)(b)”, delete the phrase “letters of support must be (in a separate tabbed section of the application) that indicate the nature and extent of existing or planned collaborative support” and replace it with the phrase “letters of support that indicate the nature and extent of existing or planned collaborative support may be included in the appendices.”

this level of progress toward meeting NPCR standards, they may wish to designate another organization to operate the State or Territory's cancer registry."

Page 19943, third column, section "I.2. Availability of Funds", delete all specific dollar amounts listed. New dollar amounts will be published in the annual open season announcement.

Page 19944, first column, first paragraph, delete the phrase "*** original five year project period." and replace it with "*** original project period."

Page 19944, third column, section "I.3.a.(1)" contains a note. After the first sentence in the notation, add the sentence "Benign brain-related tumors will be included in the required data collection set for cases diagnosed on or after January 1, 2004."

Page 19944, third column, and Page 19945, first column, section "I.3.a.(2) Collect all required data items.", delete the first paragraph and replace with "A complete listing of required and supplementary/recommended data to be collected or derived for invasive and in-situ cancers diagnosed on or after January 1, 2003 can be found in NAACCR Standards for Cancer Registries, Volume II Data Standards and Data Dictionary, Chapter IX; Required Status Table."

Page 19945, first column, section "I.3.a.(5)", second sentence, add the word "demonstrated", so that the sentence reads "Performance will be measured by the extent to which the program has documented and demonstrated their ability to store required data."

Page 19945, second column, section "I.3.a.(11)", second paragraph, delete the first sentence and replace with "Annually link registry files with those of the State's NCCCEDP."

Page 19946, second column, section "I.4.a.(4)(c)[1]", after the first sentence, add "In addition, please include a listing of any NPCR required data items that are not currently being collected. For each item not being collected, include an explanation of why it is not being collected."

Page 19946, second column, section "I.4.a.(4)(c)[2]", delete the first sentence.

Page 19946, second column, section "I.4.a.(4)(c)[3]", last sentence, delete "quarter for applicants currently funded by NPCR.", and replace with "year from the assessment of the NPCRSS data submission."

Page 19946, second column, section "I.4.a.(4)(c)[4]", first sentence, add the phrase "if available" so that the sentence reads, "An assessment of the quality of data for diagnosis years 1995

through 2001, if available, and a description of the method for measuring specific quality indicators."

Page 19946, third column, section "I.4.a.(4)(d)", after the first sentence, add the sentence "(Note: Inclusion of an annual report will not be counted against the 20 page limit for appendices.)"

Page 19947, first column, section "I.4.a.(5)(a)", after the first sentence, add the sentence "A copy of the organizational chart indicating the placement of the proposed program, abbreviated (one page) resumes for the designated staff, and job descriptions for the proposed staff should be included in the application as an appendix."

Page 19947, first column, section "I.4.a.(5)(d)", delete the second sentence.

Page 19947, third column, section "I.4.a.(9)(a)", add the following phrase to the end of the sentence, "to be achieved with the requested funding."

Page 19947, third column, section "I.4.a.(9)(e)", delete the phrase "*** responsible for activities." and replace it with "*** responsible for each activity."

Page 19947, third column, section "I.4.a.(9)(i)[1]", delete the sentence "If appropriate, the plan may include improving the completeness or quality of past years ***"

Page 19948, first column, section "I.4.a.(10)(b)[3]", delete the first sentence and replace with "Travel funds for up to two persons to make one, two-day, trip to Atlanta, GA for a reverse site visit."

Page 19948, second column, section "I.5.a.", in the header, correct the spelling of the word "Requirements."

Page 19948, second column, section "I.5.a.(1)", correct the third sentence to read "Cumulative data will be requested from the reference year to 12 months past the close of the most recent diagnosis year."

Page 19948, second column, section "I.5.a.(2)", second paragraph, first sentence, delete "*** NPCR's Planning Program's attainment of goals ***" and replace with " *** an NPCR Planning Program's attainment of goals ***"

Page 19948, second column, section "I.5.a.(2)(b)", second paragraph, delete the third sentence and replace with "Applications must be received by February 28 of the fiscal year in which the applicant wishes to be considered for Enhancement funding."

Page 19949, second column, section "J.1.a.(3)", first sentence. Delete this sentence.

Page 19949, second column, section "J.1.a.(4)(b) NCCCEDP:", delete the

sentence and replace with "An example that demonstrates the impact of the NCCCEDP, and updated list of the screening and diagnostic procedures paid for by the program, the amount paid and the maximum amount allowed by Medicare within the State. Also include an updated letter of assurance regarding Medicaid coverage for CBE, screening mammograms, Pap smears and pelvic exams."

Page 19949, second column, section "J.1.a.(4)(b) NPCR:", correct typographical error in section title. Section title should read "J.1.a.(4)(c) NPCR:" Before the first sentence in this section, add the sentence "A hard copy of the State's most recent annual report on cancer incidence is required."

Page 19950, first column, first paragraph, add the sentence "Updated contact information and appendices will be published annually in the open season announcement."

Sandra R. Manning,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0109]

Agency Information Collection Activities; Announcement of OMB Approval; Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT:

Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 16, 2002 (67 FR 58429), the agency announced that the proposed information collection had been submitted to OMB for review