UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL CENTER FOR ENVIRONMENTAL RESEARCH
WASHINGTON, DC 20460

SEP 1 4 2004

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: Protection of Human Subjects Certification

FROM: Peter W. Preuss, Ph.D. PW Preuss
Director
National Center for Environmental Assessment (8601D)
EPA Human Subjects Research Review Official

TO: Harold Zenick, Ph.D.
Associate Director for Health, NHEERL (B 105-01)

I have reviewed this proposal and am satisfied that it complies with EPA Regulation 40 CFR 26 **PROTECTION OF HUMAN SUBJECTS,** and with EPA Order 1000.17, Change A1, **Policy and Procedures on Protection of Human Subjects.**

EPA No: husulg# 04-45 ✓

APPLICANT: NHEERL, Univ. of North Carolina

PROJECT TITLE: *Physiological Changes in Adults with Metabolic Syndrome Exposed to Concentrated Ultrafine Chapel Hill Air Particles*

PRINCIPAL INVESTIGATOR: Don Graff, Ph.D.

PROJECT OFFICER: Don Graff, Ph.D.

cc. McDonnell (MD-58B)
Graff (MD-58A)

09/14/04 TUE 15:42 FAX 2025650090 002

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Health and Environmental Effects Research Laboratory
Research Triangle Park, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

August 17, 2004

MEMORANDUM

SUBJECT: Approval for Human Research Protocol entitled: "Physiological Changes in Adults with Metabolic Syndrome Exposed to Concentrated Ultrafine Chapel Hill Air Particles" (GCRC # 2067)

FROM: Harold Zenick, Ph.D.
Associate Director for Health, NHEERL (B105-01)

TO: Peter Preuss, Ph.D.
Director, NCEA (8701R)

THRU: Roger S. Cortesi. Ph.D.
Peer Review Compliance Executive, NCER (8701R)

The subject protocol is attached for your review of compliance with Federal human research ethics requirements. My staff and I believe that it complies fully with the Common Rule. If you have any questions, please contact Dr. William McDonnell at (919) 966-6220. Thank you.

cc: **Dr. McDonnell**

Attachment