UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH AND ENVIRONMENTAL EFFECTS RESEARCH LABORATORY
OFFICE OF RESEARCH AND DEVELOPMENT
RESEARCH TRIANGLE PARK, NC 27711

Date: May 24, 2010

MEMORANDUM

SUBJECT: IRB Study # 09-1344

FROM: Tina Stevens, Ph.D.; Micheal Madden, Ph.D.; David Diaz-Sanchez, Ph.D.;
Environmental Public Health Division

THROUGH: Tim Watkins, MS
Acting Director
Environmental Public Health Division

TO: R. Julian Preston, Ph.D.
Associate Director for Health
NHEERL

Approved
5-28-10

The purpose of this study is, first, to examine whether DE can alter lung and cardiovascular responses to O3 exposure when given a day before or during O3 exposure; second, to investigate if co-exposure of DE and O3 on day 1 augment the lung function decrements following a subsequent O3 exposure (day 2); third, to investigate if two consecutive days of O3 affect individual cardiovascular responses such as changes in heart rate variability (HRV) and blood pressure (BP), to ozone in young healthy adults.

This is a request for review and approval of human study research protocol # 09-1344. I have revised the research protocol and consent form to address the concerns put forth by Warren Lux.
Within this packet, I have submitted the following documents

- Cover memo
- NHEERL sign-off sheet with signatures
- NHEERL Fact Sheet
- NHEERL Study Justification Document
- IRB approval letter final
- IRB modification form
- IRB modification approval letter
- Marked copy of research protocol

- Research protocol as approved by the IRB
- Marked copy of consent form
- Consent form approved and stamped by the IRB
- Storage consent form approved and stamped by the IRB
- Questionnaires and advertising approved and stamped by the IRB
- Ethics training reports required by the IRB
- Copies of extramural scientific reviews and responses

Thank you for your consideration, if you have further questions, please let me know.

APPENDIX A

NHEERL HUMAN RESEARCH SIGN-OFF SHEET

PI *(Name/Division)*: Tina Stevens / EPHD

PROTOCOL TITLE: Cardiopulmonary responses to exposure to ozone and diesel exhaust with moderate exercise in healthy adults

NAME OF APPROVING IRB: UNC IRB

IRB-ASSIGNED PROTOCOL NUMBER: 09-1344

REVIEWS *(Attach to EPA Protocol Package)*		
Reviewer	**Signature**	***Date***
Peer Reviewer1 (printed or typed)	W. Michael Foster	7/30/09
Peer Reviewer2 *(printed or typed)*	Bill Linn	7/09
Statistician	AG Rappoll	5/21/10
Physician	[illegible]	5/21/10
Other		
APPROVALS		
Official	**Signature**	**Date**
Branch Chief	[illegible]	5/24/10
IRB	*(Attach signed approval letter)*	
Dosing Review Officer (if applicable)	N/A B. Michael Gray	5/21/10
Division Quality Assurance Officer	B. Michael Gray	5/21/10
HRPO Director	[illegible]	5.23.10
Division Director	[illegible]	5/27/10
Associate Director for Health	*(Indicated by approval letter)*	
Agency Human Subjects Research Review Official	*(Indicated by approval letter)*	

revised 5/15/2008