



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
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<https://my.research.unc.edu> for IRB status
Federalwide Assurance (FWA) #4801

To: Haiyan Tong
Environmentally Protection Agency
CB# 7315

From: Biomedical IRB

Authorized signature on behalf of IRB

Approval Date: 5/26/2010
Expiration Date of Approval: 1/24/2011

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Unanticipated Problem
Expedited Category: Minor Change to Previously Approved Research
Study #: 07-0190
Other #: CTRC : 2579
Study Title: GCRC-2579: Cardioprotective Effects of Omega-3 Fatty Acids Supplementation in Healthy Older Subjects Exposed to Air Pollution Particles
Sponsors: EPA Intramural Federal Research

This submission has been approved by the above IRB for the period indicated. It has been determined that the risk involved in this modification is no more than minimal. Unless otherwise noted, regulatory and other findings made previously for this study continue to be applicable.

Submission Description:

A study subject (OMC-029) had intermittent atrial and ventricular ectopy. No symptoms. Submission includes details of event, as requested by IRB. No further action is needed.

Investigator's Responsibilities:

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
James Samet, Environmentally Protection Agency
Robert Truckner, (EPA), Non-IRB Review Contact
Wanda Simmons, (CTRC), Non-IRB Review Contact

**Response to Minor Stipulations
Adverse Event**

Receipt Date : 5/25/2010

Expiration Date : 1/24/2011 Previous Review Type: **Renewal Full Board**

IRB: Biomedical

PI: Haiyan Tong

IRB ID : 07-0190

IRB Admin : Ina Friedman

Title: GCRC-2579: Cardioprotective Effects of Omega-3 Fatty Acids Supplementation in Healthy Older Subjects Exposed to Air Pollution Particles

Full Board Review

Not Full Board Review

Study Description :

The purpose of this study is to identify an optimal concentration of diesel exhaust which can be used to study the risks of cardiac changes in healthy older subjects. Healthy adults, ages 50 to 75 years, will complete seven visits over 18-20 weeks.

Submission Description :

A study subject (OMC-029) had cardiac arrhythmia.

*Thank + Approve.
No further action needed.
It*

PROCESSING STEPS (OFFICE USE ONLY):

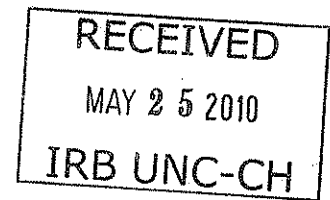
- Reviewer Checklist completed
- Minor Stipulation letter:
 - Draft letter prepared
 - Approved by chair as attached (Initials/Date: _____)
 - Approved by chair, see edits (Initials/Date: _____)
 - Email copy sent
 - Hard copy sent
- Approval letter:
 - Draft letter prepared
 - Approved by chair as attached (Initials/Date: *9a 5/26/10*)
 - Approved by chair, see edits (Initials/Date: _____)
 - Email copy sent *IT*
 - Hard copy sent *IT*

Consent forms attached: _____
Other attachments: _____ *IT*

FINAL ACTIONS:

- Approved *9a 5/26/10*
- Approved with Minor Stipulations
- NHSR
- Return to Full IRB
- Return to sender
- Closure

To: IRB
CB# 7097, Medical Building 52
105 Mason Farm Road
Chapel Hill, NC 27599-7097



From: Haiyan Tong
Environment Protection Agency
CB# 7315
E-mail: tong.haiyan@epa.gov
Phone number: 966-4993

May 25, 2010

Study #: 07-0190

Other #: CTRC: 2579

Study Title: Cardioprotective Effects of Omega-3 Fatty Acids Supplementation in Healthy Older Subjects Exposed to Air Pollution Particles

Dear IRB review committee,

Thanks for the Board Review of an unanticipated problem report submitted to IRB on May 25, 2010. Below are a point-by-point responses to the items listed in the "Contingencies to be addressed following IRB review on May 25, 2010".

What was the duration of exposure at the time the arrhythmia was noted?

The subject was exposed to two-hour of filtered air which is the clean air control of the air pollution exposure study. The arrhythmia was noted on the telemetry right after the filtered air exposure began.

What was the nature and duration of the cardiac arrhythmia?

Intermittent premature ventricular contraction (PVC) and supraventricular ectopy were noticed during the 2 hrs of exposure session. The Holter monitor data collected from 8 am on May 24 to 8 am on May 25 showed that the PVC and supraventricular ectopy were presented throughout the 24 hr period.

Was the subject symptomatic?

The subject had no symptom with arrhythmia.

What treatment and follow up were recommended, if any?

In consideration of clean air exposure does not cause cardiac arrhythmia and the subject was symptom free, we did not treat the subject. However, the subject was counseled for his arrhythmia and provided a copy of the Holter monitor report and advised to see his own primary physician for further investigation.

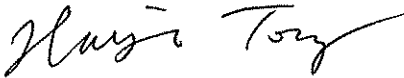
Was there anything in the subject history to indicate risk or prior occurrence?

The subject had no history of arrhythmia. The ECG was normal on the pre-study physical exam which was evaluated by a cardiologist.

The unanticipated problem reported is specific to this subject. We do not revise the study protocol, consent forms, and recruitment materials at this time.

Please let me know if you have any further questions.

Sincerely,

A handwritten signature in cursive script that reads "Haiyan Tong". The signature is written in black ink and is positioned above the printed name.

Haiyan Tong

IRB Notice

IRB

to:

Haiyan Tong

05/25/2010 02:02 PM

Cc:

James Samet, Robert Truckner, wsimmons+IRB

Show Details

To: Haiyan Tong

Environmentally Protection Agency

CB# 7315

From: Biomedical IRB

Date: 5/25/2010 **RE:** Contingencies to be addressed following IRB review of unanticipated problem report

Submission Type: Unanticipated Problem

Study #: 07-0190

Other #: CTRC : 2579

Study Title: GCRC-2579: Cardioprotective Effects of Omega-3 Fatty Acids Supplementation in Healthy Older Subjects Exposed to Air Pollution Particles

Submission Description:

A study subject (OMC-029) had cardiac arrhythmia.

The IRB has reviewed your unanticipated problem report and determined that changes to the study are warranted as described below. Please address these changes in a cover memo that includes a point-by-point response to the item(s) listed and attach any revised study documents, including protocol, consent forms, recruitment materials, etc.

When you respond, please be sure to cite the IRB study number noted above, and indicate that you are responding to an unanticipated problem report. Failure to link your response to this study, in general, and this memo, in particular, may result in delays. Any additional changes beyond what has been requested (including new materials) must also be listed and discussed in the memo. Please submit 2 copies of all revised materials, one in which all changes are underlined and the other a "clean" copy with no underlining.

Study Specific Details:

Please provide additional information. What was the duration of exposure at the time the arrhythmia was noted? What was the nature and duration of the cardiac arrhythmia? Was the subject symptomatic? What treatment and follow up were recommended, if any? Was there anything in the subject history to indicate risk or prior occurrence?

CC:

James Samet, Environmentally Protection Agency

Robert Truckner, (EPA), Non-IRB Review Contact

Wanda Simmons, (CTRC), Non-IRB Review Contact

IRB Informational Message—please do not use email REPLY to this address