

## Recruitment Script

### Study Restrictions:

In addition to the timing of the study, you must be willing to observe several important restrictions. They are:

- No use of over the counter pain medications such as aspirin, Advil, Aleve or other non-steroidal anti-inflammatory medications for 2 weeks prior to all visits. Low-dose aspirin and Tylenol (acetaminophen) are permitted.
- No intake of omega-3 fatty acids or having more than one 4-6 oz/serving of all types of fish and shellfish, walnuts, flaxseeds and flaxseed oil, rapeseed oil, canola oil, soybeans and soy products, Eggland's Best eggs, and cod liver oil for two weeks before and during the study.
- No intake of antioxidants (e.g., beta-carotene, selenium, vitamin C, vitamin E, zinc) for two weeks before and during the study.
- Must be willing to use olive oil for cooking, dressings, and sauces during the study.
- Must avoid drinking red wine during the study.
- Avoid smoke and fumes for 24 hours before all visits.
- Avoid drinking alcohol 24 hours before all visits.
- Avoid strenuous exercise for 24 hours prior to and after all visits.
- On the exposure day, you should eat a light breakfast.
- Must not eat pan fried and/or grilled foods after midnight prior to the exposure day.
- No caffeine for 12 hours prior to all study visits.
- Due to the overnight heart monitor must be willing to refrain from bathing between exposure and follow-up.

Would you be able to comply with these restrictions? If so, we can schedule you for an office visit to complete the initial part of the screening.

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### Study Schedule

Genotyping Visit, days/times TBD (less than 1 hour)

Medical History Screening, to be completed at home and mailed (1 hour)

Physical Exam, days and times TBD (2 hours)

Training (Day 0): (3 hours)

Dietary Supplementation (Days 0-14)

Training Follow-up Visit Day 1 (to return the Holter Monitor, 30 min)

Dietary Recordings, Days 3-5 and Days 11-13

Exposure Day 15: 8:00 AM (8 hours)

Follow-up Day 16: 18 hours after Exposure Day (3 hours)

EX. 2

**OMEGA STUDY**  
**E-mail Announcement**

**SUBJECT: INFORMATIONAL: Research study for Healthy Older Adults**

The main purpose of this research study is to determine if a component of air pollution, particulate matter (PM) elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Volunteers ages 50 to 75 will be tested to determine the type of a particular gene they carry, one of several genes responsible for protecting the body against oxidants such as diesel exhaust. Participation will include two-weeks of fish oil or olive oil treatments and one exposure to a controlled amount of PM. For more information, please visit our web site at [www.epastudies.org](http://www.epastudies.org) or call Westat EPA Recruiting at 966-0604.

Approved [date] by the Committee on the Protection of the Rights of Human Subjects Biomedical Institutional Review Board. IRB # 07-0190 (GCRC #2579).

This email is sponsored by: U.S. Environmental Protection Agency Human Studies Division located on the UNC-Chapel Hill campus.

APPROVED - IRB UNC-CH

AUG 26 2008

EX. 2

The US Environmental Protection Agency is seeking

## **ADULT VOLUNTEERS**

**Ages 50 to 75 for Research**

**This is a research study about genetics,  
diet supplementation and exposure  
to air pollution.**

We are looking for healthy older adults to study diet  
supplementation and the effects of air pollution  
exposure on heart and lung function.

Total time commitment after screening is about 14 hours over 4 to  
5 weeks. You will receive payment for screening, the study, and  
out of town travel. Parking is provided.

**1-888-279-9353 or  
919-966-0604  
[www.epastudies.org](http://www.epastudies.org)**



The Human Studies Facility is located on the UNC-CH campus

APPROVED FOR UNC-CH

AUG 26 2008

EX.2

Web Site Advertising: [www.epastudies.org](http://www.epastudies.org)

### **OMEGA: Elder Diet and Air Pollution Study**

This is a study for healthy 50 to 75 year old adults. The main purpose of this research study is to determine if a component of ambient air pollution to which we are all exposed, particulate matter (PM), elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Results from this study may increase the understanding of how gaseous and particulate air pollutants (which causes the haze seen in some polluted cities) may adversely affect the functioning of the human cardiovascular and respiratory systems. This understanding may be especially important for patients with cardiopulmonary diseases. As a volunteer you will undergo a blood test to determine the type of a particular gene you carry. This gene, (GSTM1, glutathione-S-transferase) is one of several genes responsible for protecting your body against oxidants such as PM, and some recent studies have shown that people carrying a mutation in this specific gene, which renders this gene inactive, may be more susceptible to the effects of air pollutants.

Participation in this study will include two-weeks of fish oil or olive oil treatments and one exposure to a controlled amount of air pollution particles, no more than you might encounter if you visited a large city such as Los Angeles, New York, or Mexico City on a smoggy day. Study procedures include breathing tests, heart rate monitoring, blood tests, and ultrasound imaging of an artery in your arm. During the ultrasound procedure you will also be given a dose of nitroglycerine, which is a short-acting vasodilator. Total time commitment after screening is about 15 hours, over 4-5 weeks. Compensation is provided.

APPROVED - IRB, UNC-CH

AUG 26 2008

EX. 2

**TO:**

**RE: Your appointment at the EPA Human Studies Facility**

**STUDY: OMEGA STUDY – GENOTYPING VISIT**

**DATE:**

**TIME:**

APPROVED \_\_\_\_\_ NC-CH

AUG 26 2008

**SPECIAL NOTICE**

**If you are a UNC Student or are UNC staff or faculty:  
you MUST print this appointment slip and display it on the dashboard in your car.**

**If you do not display it, you will be ticketed.**

[Parking information to be provided here as available.]

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**OMEGA STUDY SCREENING GUIDELINES  
For Genotyping Visit**

**Illness.** If you are sick or have been sick or injured in the last 4 weeks, please call Recruitment at 966-0604 or 888-279-9353. This includes sore throats, coughs, colds, and cold sores.

**No active allergies.** If you have questions about allergies, please call the EPA medical station at 966-6232.

Please do not **EAT or DRINK** anything except water after midnight the day of your visit.

If you are unable to keep your appointment, please call Recruitment. Please be on time!

Thank You!  
Westat EPA Support Services



**TO:**

**RE:** Your appointment at the EPA Human Studies Facility

**STUDY:** OMEGA STUDY - EXPOSURE VISITS

**DATE:**

**TIME:**

APPROVED FOR UNC-C

AUG 26 2008

**SPECIAL NOTICE**

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**OMEGA Study Instructions  
For Exposure and Follow-up Visits**

**Illness and Allergies.** If you are sick or have been sick or injured in the last 4 weeks, please call Recruitment at 966-0604 or 888-279-9353. This includes sore throats, coughs, colds, and cold sores. If you have questions about allergies, please call the EPA medical station at 966-6232.

**Medications**

- No over the counter pain medications such as aspirin, Advil, Aleve or other non-steroidal anti-inflammatory medications for 2 weeks prior to all visits. Low-dose aspirin and Tylenol (acetaminophen) are permitted.

**Smoke, Alcohol and Caffeine**

- Avoid smoke and fumes for 24 hours before all visits.
- Avoid drinking alcohol 24 hours before all visits. No red wine throughout the study.
- No caffeine for 12 hours prior to all study visits.

**Food and Food Supplements**

- No omega-3 fatty acids or having more than one 4-6 oz/serving of all types of fish and shellfish, walnuts, flaxseeds and flaxseed oil, rapeseed oil, canola oil, soybeans and soy products, Eggland's Best eggs, and cod liver oil for 2 weeks before and during the study.
- No antioxidants (beta-carotene, selenium, vitamin C, vitamin E, zinc) for 2 weeks before and during the study.
- Use olive oil only for cooking, dressings, and sauces during the study.
- On the exposure day, eat a light breakfast.
- Do not eat pan fried and/or grilled foods after midnight prior to the exposure day.

**Exercise, Clothing**

- No strenuous exercise for 24 hours prior to and after all visits.
- Do not apply lotions, powders or perfumes to your chest.
- Wear comfortable washable clothing (button front shirt), socks and bring a light jacket or sweat shirt.
- Do not bathe or shower between the exposure and follow-up visits.

If you are unable to keep your appointment, please call Recruitment. Please be on time!

Thank You!

Westat EPA Support Services

AUG 26 2008

**TO:**  
**RE:** Your appointment at the EPA Human Studies Facility  
**STUDY:** OMEGA STUDY – TRAINING VISIT  
**DATE:**  
**TIME:**

**SPECIAL NOTICE**

**If you are a UNC Student or are UNC staff or faculty:**  
**you MUST print this appointment slip and display it on the dashboard in your car.**  
If you do not display it, you will be ticketed.

[Parking information to be provided here as available.]

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**OMEGA Study Instructions  
For the Training Visit**

**Illness and Allergies.** If you are sick or have been sick or injured in the last 4 weeks, please call Recruitment at 966-0604 or 888-279-9353. This includes sore throats, coughs, colds, and cold sores. If you have questions about allergies, please call the EPA medical station at 966-6232.

**Medications**

- No over the counter pain medications such as aspirin, Advil, Aleve or other non-steroidal anti-inflammatory medications for 2 weeks prior to the training visit. Low-dose aspirin and Tylenol (acetaminophen) are permitted.

**Smoke, Alcohol and Caffeine**

- Avoid smoke and fumes for 24 hours before training.
- Avoid drinking alcohol 24 hours before training. No red wine throughout the study.
- No caffeine for 12 hours prior to training.

**Food and Food Supplements**

- No omega-3 fatty acids or having more than one 4-6 oz/serving of all types of fish and shellfish, walnuts, flaxseeds and flaxseed oil, rapeseed oil, canola oil, soybeans and soy products, Eggland's Best eggs, and cod liver oil for 2 weeks before TRAINING and during the study.
- No antioxidants (beta-carotene, selenium, vitamin C, vitamin E, zinc) for 2 weeks before TRAINING and during the study.
- Use olive oil only for cooking, dressings, and sauces during the study.
- You must begin your daily dietary supplements on \_\_\_\_\_ [day], \_\_\_\_\_ [date].

**Exercise, Clothing**

- No strenuous exercise for 24 hours prior to and after TRAINING and all visits.
- Do not apply lotions, powders or perfumes to your chest.
- Wear comfortable washable clothing (button front shirt), socks and bring a light jacket or sweat shirt.
- Do not bathe or shower between the training and follow-up visit.

If you are unable to keep your appointment, please call Recruitment. Please be on time!

Thank You!

Westat EPA Support Services

**OMEGA STUDY**  
**IRB # 07-0190 GCRC #2579**

AUG 26 2008

**Purpose:**

The main purpose of this research study is to determine if a component of ambient air pollution to which we are all exposed, particulate matter (PM), elevates the risks of cardiac changes and whether fish oil supplements will lessen the risks caused by PM. Results from this study may increase the understanding of how gaseous and particulate air pollutants (which causes the haze seen in some polluted cities) may adversely affect the functioning of the human cardiovascular and respiratory systems. This understanding may be especially important for patients with cardiopulmonary diseases.

Some of your blood will also be used to determine the type of a particular gene you carry. This gene, (GSTM1, glutathione-S-transferase) is one of several genes responsible for protecting your body against oxidants such as air pollutants, and some recent studies have shown that people carrying a mutation in this specific gene, which renders this gene inactive, may be more susceptible to the effects of air pollutants.

This study is for healthy adults ages 50 to 75. Payment for the study is incremental with a maximum total of \$1225.

**Procedures:**

Volunteers initially undergo a blood test and genotype screening, followed by routine medical screening at the EPA Human Studies Facility, which includes completing medical history forms and a physical exam. You will be paid \$30 for the genotyping visit and \$30 for the additional medical screening. If you are eligible for the study your participation will last approximately 4 to 5 weeks.

Participation will begin with a training visit that will last about 3 hours and a return visit the following morning. Following training you will be scheduled for two-weeks of fish oil or olive oil treatments (taken as capsules) prior to the exposure session. During each week that you take the supplements you will be asked to record your food intake twice for 3 days each. The exposure day lasts 8 hours and the follow up day lasts about 3.

Procedures involved in this study include breathing tests, heart rate monitoring, including wearing overnight monitors after training and the exposure, blood draws, and ultrasound imaging of an artery in your arm. During the ultrasound procedure you will also be given a dose of nitroglycerine, which is a short-acting vasodilator. You will be exposed to a controlled amount of air pollution particles, no more than you might encounter if you visited a large city such as Los Angeles, New York, or Mexico City on a smoggy day. You will be asked to wear a heart rate monitor over night following exposure sessions.

The timing of this study is important: you must be able refrain from certain foods and medications for at least four weeks and to take the supplements for 15 days prior to the exposure. Does this sound like something that you would be interested in doing?

*If yes, proceed to eligibility screening (IRB #95-0518, previously 95-EPA-66). Study specific inclusion/exclusion criteria appear in the IRB application (#GCRC 2579).*

EX 2