University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Subjects

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Biomedical Form

IRB Study #____07-0190____ GCRC #: 2579
Consent Form Version Date: May 6, 2010

Title of Study: Cardioprotective Effects of Omega-3 Fatty Acid Supplementation in Healthy Older Subjects Exposed to Air Pollution Particles
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Faculty Advisor: James M Samet, PhD, MPH
Funding Source: US Environmental Protection Agency Intramural Federal Research
Study Contact telephone number: 966-4993
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What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason at any time.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Your participation is voluntary. Deciding not to be in the study or leaving the study before it is completed will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a

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copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

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 (heart and blood vessels) and respiratory (lungs) 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, glutathione-S-transferase (GSTM1) is one of several genes responsible for protecting your body against oxidants such as air pollutant, and some recent studies have shown that people carrying a mutation in this specific gene, which renders this gene inactive maybe more susceptible to the effects of air pollutants.

You are being asked to be in this study because:

- You are 50-75 years old, generally healthy.
- You have a normal resting electrocardiogram (ECG).
- Your oxygen saturation is greater than 94% at the time of physical exam.

Are there any reasons you should not be in this study?

You should not participate in this study if…

- You have a history of chest pain, irregular heart beats, heart failure, and heart attack or coronary bypass surgery.
- You have a heart pacemaker.
- You have untreated high blood pressure (> 150 systolic, > 90 diastolic).
- You have a history of chronic lung diseases such as chronic obstructive pulmonary disease or severe asthma.
- You have a history of migraine headache.
- A history of rheumatologic diseases or immunodeficiency state,
- You have allergies to fish or omega-3 fatty acids.
- You are on doctor's orders to take fish oil that we do not want to interfere with your therapy.
- You are currently taking β-blockers (such as atenolol, metoprolol, propanolol, and acebutolol).
- You have a history of bleeding or coagulation disorders and are taking blood thinner medication.
- You are currently smoking or have a smoking history within 1 year of the study (defined as more than one pack of cigarettes in the past year) or have a greater than/equal to a 5 pack year smoking history.
- You are a diabetic.
- You have cancer (exception for history of nonmelanoma skin cancer).

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- You are pregnant, attempting to become pregnant or breastfeeding.
- You have an allergy to latex.
- History of skin allergy to tape or electrodes.

You should **NOT** participate if you are unable to comply with the following requirements:

- No over-the-counter pain medications such as aspirin, Advil, Aleve or other non-steroidal anti-inflammatory medications for 2 weeks prior to exposure. Low-dose aspirin and Tylenol (acetaminophen) are permitted.
- 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 two weeks before and during the intervention period.
- No antioxidants (eg, beta-carotene, selenium, vitamin C, vitamin E, zinc) for two weeks before and during the intervention period.
- Use olive oil for cooking, dressings, and sauces during the intervention period.
- Avoid drinking red wine during fish oil/placebo intervention period.
- 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.
- Eat a light breakfast on the exposure day.
- Not eat pan fried and/or grilled foods after midnight prior to the exposure day.
- Not consume caffeine for 12 hours prior to all study visits.

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 32 people in this research study.

How long will your participation in this study last?

You will have up to 6 visits to the research facility over approximately 6-7 weeks if you are eligible for the study (see attached study design flow chart).

Your participation in this study will include two parts: 1) four-week of fish oil/olive oil treatments, and 2) exposure part. Exposure part include one training session (today) for about 3 hours, and two exposure sessions which last approximately 8 hours each, and one session 18 hours after air pollution exposure which last approximately 3 hours.

Storage of some of your blood samples in this study may be indefinite.

What will happen if you take part in the study?

Before you agree to participate in this study, you must read the consent form in its entirety. The research and medical staff will then answer all of your questions and explain all of the risks involved in this study to your satisfaction.

You should have already undergone an initial screening visit and a general physical examination to ensure that you are a candidate for this study. If you are a female participating in this study, you should have been asked about your menstrual history. You will have a pregnancy test today

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and you will have another pregnancy test on exposure day if it is more than 7 days since today's pregnancy test.

Today's visit is expected to last about 3 hours. We will review the inclusion and exclusion criteria and any medical conditions that you have or medications that you are currently taking. We will go over the study in detail so that you will know what we will expect from you as a participant and what you should expect from us as investigators. If you agree to participate in the study you will sign 2 copies of the study consent form and we will give one copy to you.

We will then train you on a breathing instrument to prepare you for your exposure session. This is known as spirometry, and you will breathe through a filter into the instrument. We will coach you, and you will be asked to take a full breath in and then blow it out as hard and fast as you can. We will ask you to do this several times. Then we will check your resting breathing rate. You will tour the exposure chambers (one for air exposure and the other for air pollution exposure) and the height of your mouth while seated in the exposure chamber will be measured so that the particle tubing height can be adjusted.

After these tests have been successfully performed, and if you are deemed to be a suitable candidate and you decide to participate in this study, you will undergo a dietary assessment on what food you have had in the last two weeks. You will be scheduled for a four-week fish oil or olive oil supplementation and the exposure session. You will be given a four-week supply of either fish oil or olive oil tablets. Please take 3 pills at dinner each day. You and your research team will not know what supplements you have received. A list of medications, environmental exposures, and foods to avoid in the next four weeks will be given to you. You will be asked to keep 3-day food records (one 3-day record per week in the study) 2 times during supplementation. We will provide a handout for you with instructions on how to complete the record, including instruction on how to estimate portion sizes with photographs of various portion sizes. You will be contacted by phone for clarification of ambiguous information. You will be rescheduled if you have experienced an illness and you have to stop taking the pills during this four weeks of supplementation period. We will give you another four weeks supply of either fish oil or olive oil tablets and you will need to restart the pills again.

Exposure days

We will call you a few days before the exposure session to remind you of your scheduled visit. We will also remind you to refrain from alcohol, excessive amounts of caffeine, and from any activities where you could be exposed to high levels of pollutants (e.g., cigarette smoke, paint fumes) for a couple of days before your visit. You should not eat pan fried or grilled meat after midnight of the exposure day.

You will be asked to eat a light breakfast and arrive at the EPA medical station at approximately 8 am.

Prior to exposure, you will:

- Have your vital signs checked (heart rate, respiratory rate, blood pressure, oxygen saturation level, and a symptom questionnaire).
- Have your heart rate viability (HRV) measured by a Holter monitor. You will have several ECG leads attached to your chest. It may be necessary to clean and

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shave the areas of your chest where these leads will be placed. Excessive deodorant, skin lotions, and body sprays may interfere with the function of some of these leads so we will ask you to not apply these to your chest area on the day you report to the HSF. The leads will be connected to 2 monitors (small recording devices about the size and weight of a portable tape player) to obtain readings of your heart rate and rhythm. One of these monitors will be removed at the end of the day and the other monitor will be kept on you until you return the next day. You will be asked to recline quietly and breathe at a constant rate for 20 minutes, after which the ECG monitor will take a 10-minute measurement of your heart rhythm. It is important that you do not fall asleep during this 30-minute period. The following morning during your next visit to the facility, there will be a 30 minute measurement of your heart rate and then the monitor will be removed. These monitors will allow us to determine if PM causes small changes in the ability of your nervous system to regulate how your heart beats. You will return to the HSF about 48 hr later to get the monitor removed. Please avoid any strenuous activities while you are wearing this monitor.

- Have your blood pressure and heart rate measured intermittently by a blood pressure monitor. You will wear a pressure cuff and a monitor which is about the size of the Holter monitor. Please keep your arm relaxed and still when the pressure cuff is inflated. We will remove the monitor and pressure cuff at about 48 hr later.
- Have about 80 ml blood drawn (about 5 1/3 tablespoons). We will test this blood to see if PM affects the ability of your blood to clot correctly, or changes proteins on the surface of blood cells. **With your permission, we may also store some of your blood we obtained during the study for yet-to-be-determined tests in the future.**
- We will take you to the General Clinical Research Center (GCRC) of North Carolina Memorial Hospital (NCMH) where we will conduct an ultrasound of an artery in your arm. The ultrasound operator will scan your arm with probe and then place a tourniquet on your arm, much like a cuff used to measure blood pressure. Measurement of the size of the artery will be made four times. First, you will be asked to rest quietly for 15 minutes, and then the first 90 second scan will be performed. Then the blood pressure cuff on your arm will be inflated for 5 minutes in order to stop the flow of blood. You may feel sensations similar to those when your foot "goes to sleep", such as "pins and needles" and tingling. After the pressure is released, a second scan will be taken of the artery. You will rest quietly for another 10 minutes, and a third ultrasound scan will be taken at the end of this rest period. You will then be given a dose of nitroglycerin under your tongue. This drug takes effect very quickly and is sometimes associated with a short-lasting headache or dizziness. Three minutes later, the final ultrasound scan will be made. You will then be asked to rest quietly for 5 minutes so that the effects of the drug will wear off before you leave the laboratory.
- Have a breathing test (spirometry). You will breathe through a filter into the machine. We will coach you, and you will be asked to take a full breath in and then blow it out as hard and fast as you can. We will ask you to do this several times.

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- You will then enter the exposure chamber and be exposed to PM.

During the exposure, you will:

You will wear a face mask in a chamber under exposures of 2 hours duration to clean air on the first day then to concentrated Chapel Hill air particles on the second day; the amount of particles you will be exposed to is less than what you would likely encounter over 24 hours on a smoggy day in an urban area. The exposure chamber is 4 ft wide by 6.25 ft in height, and is 8 ft in length. Chamber conditions will be at a comfortable temperature and relative humidity. A physician or other trained person will be seated outside the chamber observing you at all times. During the exposure, your heart will be monitored and the amount of oxygen present in your blood will be monitored by placing a device (pulse oximeter) on your finger. Your blood pressure will be measured intermittently.

If it appears you are experiencing significant discomfort, breathing or heart problems, the exposure will be terminated immediately. **In addition, you may elect to terminate the exposure at any time for any reason.** If you do so, you will be paid in full for that day's session, but will be ineligible for further participation in the study and any payments you would have received for future participation.

Immediately following the exposure, you will:

- Have your vital signs checked.
- Have a breathing test (spirometry). You will breathe through a filter into the machine. We will coach you, and you will be asked to take a full breath in and then blow it out as hard and fast as you can. We will ask you to do this several times.
- You will recline quietly for 20 minutes, after which the ECG monitor will take a 10-minute measurement of your heart rhythm.
- Have blood drawn (about 80 ml or about 5 1/3 tablespoons).
- Fill out a symptom score questionnaire.
- Have another BAU measurement at GCRC.
- Be assessed and discharged by the nursing staff.

Importantly, because you will be asked to wear the portable ECG monitor attached to your chest until you return on the follow-up day, for your safety you should not shower or bathe until after the monitor is removed. However, you will be given an instruction to follow if you need to have a shower or bath.

Eighteen hours after PM exposure follow up visit (about 3 hours)

You will return to the HSF the next morning (approximately 18 hours after PM exposure) and you will:

- Have your vital signs checked.
- Have a breathing test (spirometry). You will breathe through a filter into the machine. We will coach you, and you will be asked to take a full breath in and

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then blow it out as hard and fast as you can. We will ask you to do this several times.

- You will recline quietly for 20 minutes, after which the ECG monitor will take a 10-minute measurement of your heart rhythm.
- Have your blood pressure and heart rate measured intermittently by a blood pressure monitor and removed when you leave.
- You will have another BAU measurement at GCRC.
- Have blood drawn (about 80 ml or about 5 1/3 tablespoons).
- Fill out a symptom score questionnaire.
- Have the Holter monitor removed.

If there are any samples left over after all study information is collected, we will continue to store the samples for as yet undesignated studies. This allows us to make the best use of the samples we collect from subjects. You will be given a separate consent form for this storage, and you do not have to allow your samples to be stored indefinitely in order to participate in this study.

What are the possible benefits from being in this study?

You will not benefit directly from being in this research study, though by participating in this study you will receive a medical examination that includes blood work, respiratory test, and ECG monitoring of heart at no charge. However, this is not a substitute for a routine doctor visit. The medical staff will explain to you any remarkable findings regarding your overall health status. In addition, if we observe changes in your health status as a consequence of exposure to air pollutants, you may elect to use this information to avoid exposure on high pollution days.

This research is designed to benefit society by gaining new knowledge. Given that every member of American society is currently exposed to these pollutants, this study has the potential to contribute to devising effective strategies aimed at protecting millions from the untoward effects of these pollutants.

What are the possible risks or discomforts involved with being in this study?

This study might involve the following risks and/or discomforts to you:
If you have any tendency to become uncomfortable in small closed spaces, it is possible that you may become uncomfortable during this study. You will be taken to the exposure chamber when you are first evaluated for suitability for the study to allow you an opportunity to see where you will sit and what the chamber looks like.

PM exposure: During the exposure to the concentrated air pollution particles, you may experience some minor degree of airway irritation, cough, and shortness of breath or wheezing. These symptoms typically disappear 2 to 4 hours after exposure, but may last longer for particularly sensitive people. You will be monitored continuously during the exposure session through a window in the chamber or by closed-circuit television, and can communicate with a staff member via an intercom. Your heart rate and rhythm will also be constantly monitored for any adverse changes brought about by the exposure. A licensed physician is always on the premises during exposures, and is available to respond in an emergency. In the unlikely event that you develop medically significant symptoms, the exposure will be terminated and the

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appropriate medical intervention will be provided if required. A physician is always available to respond to an emergency and full resuscitation equipment is available for use in the event of a cardiac or pulmonary emergency.

Air pollution particles may induce an inflammatory reaction that can last for 24 hours after exposure and may increase the chance of you catching a cold. You should not engage in heavy levels of exercise for 24 hours before and after the exposure period. If you have any tendency to become uncomfortable in small closed spaces, it is possible that you may become uncomfortable during the chamber exposure. You will be taken to the exposure chamber when you are first evaluated for suitability for the study to allow you an opportunity to see where you will sit and what the chamber looks like. The chamber dimensions are 4 ft in width, 6.25 ft in height, and 8 ft in length. Although the chamber is somewhat small, it has multiple windows and you will be in constant visual contact with the investigator who will be monitoring you during the exposure. You also will be able to verbally communicate with the investigator via a microphone headset.

Supplementation: There is little risk associated with taking fish oil/olive oil supplements. You may experience allergic reaction if you have fish allergy. Fish oil/olive oil supplements will be provided by a certified vitamin company and have the same quality as the fish oil/olive oil supplements that you can buy from food store or pharmacy.

Heart rhythm monitoring: There is little risk associated with monitoring your heart by ECG or blood oxygen by pulse oximetry. However, preparing your skin for placement of adhesive ECG electrodes and removing the electrodes the next day may cause some irritation or skin discoloration, itching, or burning in some people. If this occurs you should call the nursing staff.

Venous blood sampling: The risks associated with taking blood samples are considered minimal. A well-trained member of the staff will draw the blood. Drawing blood could cause some bruising or minor pain, which usually resolves quickly. Also, a rare complication is skin infection or an infection of the vein in which the blood has been drawn. The risk of getting an infection is minimized by the use of sterile technique. If you do have signs of infection at the site (redness, warmth, painful skin, and swelling) after completion of the procedure, you will need to contact the EPA medical station.

Brachial artery ultrasound: There are no significant risks associated with ultrasound imaging of the brachial artery, or with brief episodes of forearm ischemia (reduced blood flow). Occlusion of blood flow to the arm may result in mild discomfort or temporary sensations of tingling or numbness until the blood pressure cuff is released. A small number of patients (about 1 in 200) develop a painless rash on the arm where the blood pressure cuff is placed; this disappears over several days. Sublingual nitroglycerin is a potent vasodilator, and may be associated with headache, flushing and transient lowering of your blood pressure. Since this drug is short-acting, however, these effects do not last long. To minimize the risk of low blood pressure, you will remain lying down for ten minutes after receiving nitroglycerin. As with any medication, nitroglycerin can cause an allergic reaction, such as a rash, in rare individuals. Some risks and discomforts may be unforeseeable.

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Breathing tests (spirometry): You may cough or become dizzy during these tests. You will be seated in a chair, and if these symptoms occur, they are usually only temporary. You will be exposed to low dose of acetylene for a brief period of time (single breath in and breath out), thus the risk will be quite low.

Blood pressure monitor: Similar to the regular blood pressure measurement, the risk associated with blood pressure monitor is considered minimal.

In addition, there may be uncommon or previously unrecognized risks that might occur. If you do notice any unusual symptoms occurring during the study you should call the EPA medical station or the on-call physician to report them.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?
You will be given a study code number. All electronic documents will only have that number. The paper records that the coordinators and medical doctors use may have your name. Your information can be linked to your personal information by the study number, however only study personnel have access to your personal information. Paper records that use your name are kept in a locked file cabinet in the EPA Medical Station of the Human Studies Facility. The Medical Station is locked when not attended by study staff, and the EPA Human Studies Facility has limited access to authorized individuals only, 24 hours/day for 7 days/week. Blood samples will be stored at the EPA Human Studies Facility.

Research studies may be done at many places at the same time. Your personal identifying information will not be sent to outside researchers.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

What will happen if you are injured by this research?
All forms of medical research, diagnosis, and treatment involve some risk of injury or illness. Despite our high level of precaution, you may develop an injury or illness due to participating in this study. If you develop an injury or illness determined by the on duty physician to be due to your participation in this research, the EPA will reimburse your medical expenses to treat the injury or illness up to $5000. If you believe your injury or illness was due to a lack of reasonable care or other negligent action, you have the right to pursue legal remedy. The Federal Tort Claims Act, 28 U.S.C. 2671 et. seq., provides for money damages against the United Sates when personal injury or property loss results from the negligent or wrongful act or omission of any

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employee of the EPA while acting within the scope of his or her employment. Signing this consent form does not waive any of your legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence.

If a research related injury or illness occurs, you should contact the Director of the EPA NHEERL Human Research Protocol Office at 919-966-6217.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will be paid approximately $12 per hour for your participation in this study and the total compensation for completion of this study will be approximate $1668.

If you are unable to complete the study for voluntary reasons or failure to comply with eligibility requirements you will receive full compensation for your participation up to that point.

We anticipate performing several tests on you during the course of this study. However, circumstances beyond our control may arise (i.e. equipment failure) which may prevent us from performing a specific test on you. If we are unable to perform a specific test on you which is a primary endpoint for us, you will be compensated for all tests and time completed on that day and rescheduled. If this test is a secondary endpoint for us and is also a source of compensation, you will be paid for that test, but not rescheduled to make up the procedure.

In addition, you will be reimbursed for reasonable travel expenses and for parking costs while at the research facility. Money received by participants in research studies is normally treated as ordinary income by taxing authorities and we will report payments made to you to the Internal Revenue Service as required by law. Payments totaling more than $600 in a year from a single or multiple EPA studies will be reported to the IRS. This summary is to emphasize the importance of all the visits, and to signify the importance of your time and commitment to the research study. The following table details the expected compensation for completion of the entire study:

Pre-study qualifications	
Recruitment screening	$15
Physical exam	$15
Venipuncture (~80ml)	$30
Pre-study qualification total =	$60
Training day (3 hours)	
Time (3h @$12/h)	$36
FFQ	$25
Training day total =	$61

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Exposures (2 x 8 hours)

Venipuncture (~80ml, pre, 2@$30 each)	$60
Holter monitor(2@$100 each)	$200
Chamber exposure (2 x 2 hours, 1@$72 each)	$144
Venipuncture (~80ml, post, 2@$30 each)	$60
Blood pressure monitor (2@$100 each)	$200
Time (16h @$12/h)	$192
Brachial artery ultrasound (4@$50 each)	$200
Food records (2 times)	$150
Dietary supplementation completion bonus	$50
On-time bonus (2@$25 each)	$50

Total for completion of 2 exposures = $1306

Eighteen hours after exposure (3 hour)

Venipuncture (~80ml)	$30
Time (3h @$12/h)	$36
Brachial artery ultrasound	$50
Blood pressure monitor	$25

Total for completion of post-exposure =$141
Protocol Completion Bonus $100

Approximate TOTAL for completion of study = $1668

Subjects will be provided a lunch by GCRC for the exposure day. If a subject is terminated from the study or chooses to withdraw he/she will be reimbursed for time and procedures completed up to that time point.

You should understand that your participation is voluntary. You may terminate your participation in the study at any time without penalty. If you voluntarily elect to withdraw from the study at any time or you fail to maintain compliance with eligibility requirements, you will be paid for that portion of the study that has been completed. In the event a scheduled study activity must be cancelled by the investigators with less than 72 hours prior notice, you will be paid $12 per hour for the time scheduled and canceled. You will be paid in full for any procedures that may have been started during the current visit. Cancellations could occur due to adverse weather conditions, equipment failure, and other unforeseen events. When feasible, canceled visits will be rescheduled.

The investigators also have the right to stop your participation in the study at any time. This could be because you have had an unexpected reaction, or because the entire study has been stopped, or for some other reason. If you are dismissed by the investigators prior to completion, you will be paid for the entire study excluding the completion bonus.

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Will it cost you anything to be in this study?
There will be no cost to you for participating in the study. However, if you are deemed not eligible to participate in the study for medical reasons, we may suggest that you seek follow-up care from your own health care provider for abnormalities discovered during the screening history, physical examination, or the study. **Such care is entirely at your own expense. EPA will not provide reimbursement for any follow-up care.**

All study procedures will be paid for by the study. We will give you parking coupons to cover the cost of parking. If you live beyond Chapel Hill/Carrboro you will be reimbursed for mileage at the US Government mileage rate in effect at the time.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by The U.S. Environmental Protection Agency. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have further questions regarding this study, you should call one of the listed investigators on the first page of this form.

If you feel a research-related injury has occurred, please contact the HSF medical station or one of the investigators listed above. In addition, you should contact the Human Studies Division Human Research Officer and Director of the National Health Effects and Environmental Research Laboratory Human Research Protocol Office at 919-966-6217.

What if you have questions about your rights as a research subject?
All research on human subjects is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously, if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_ subjects@unc.edu and/or the EPA Director of the National Health and Environmental Effects Human Research Laboratory Protocol Office at 919-966-6217.

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

Principal Investigator: Haiyan Tong, MD, PhD

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Subject Date

_____

Printed Name of Research Subject

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

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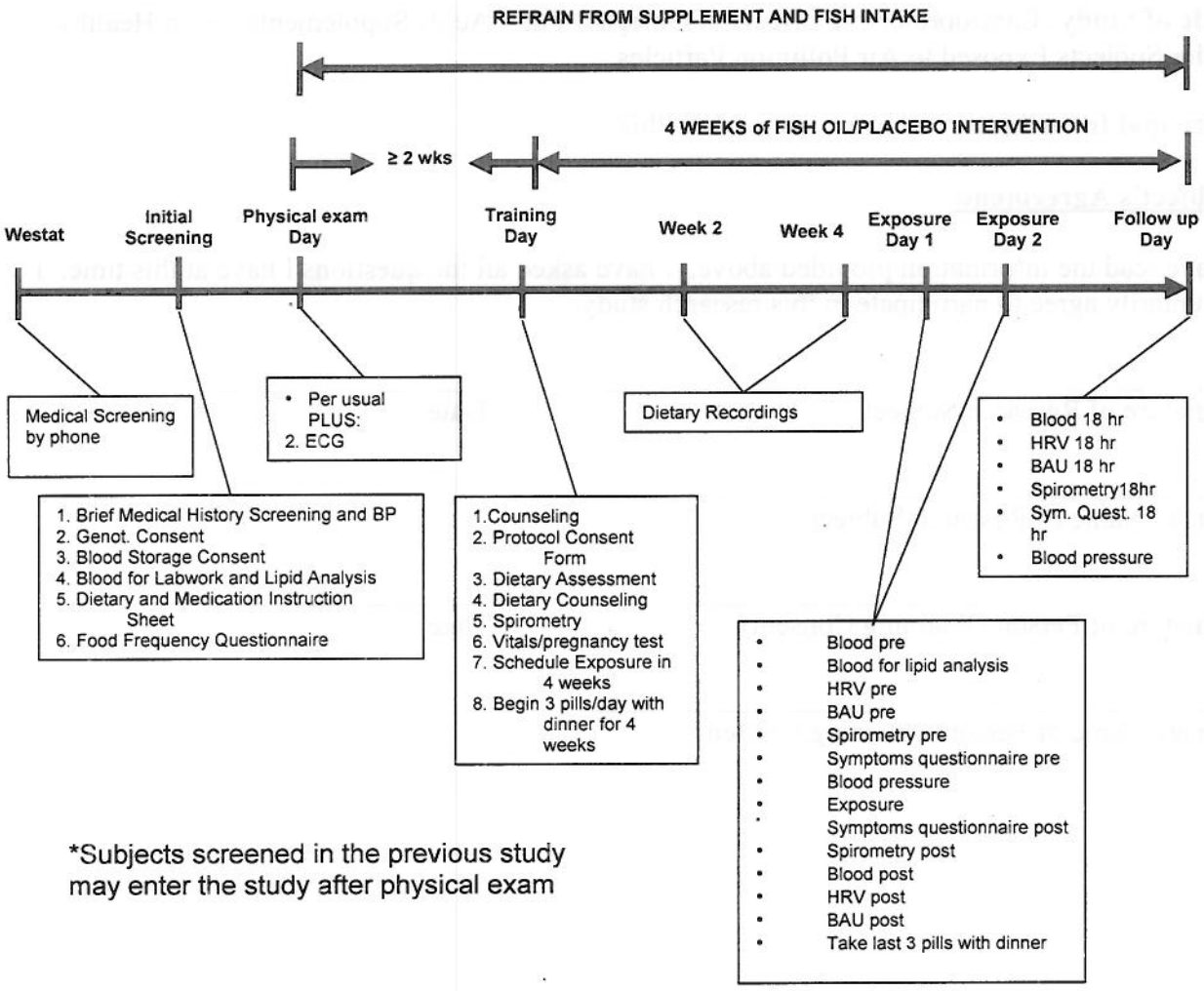

STUDY FLOW DIAGRAM

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