



December 12, 2006

Dale P. Sandler PhD
National Institute of Environmental Health Sciences (NIEHS)
111 T W Alexander Drive MSC A3-05
Research Triangle Park, NC 27709

Re: Protocol #: 02-E-N271
IRB Tracking #: SSS1-06-402

Dear Dr. Sandler,

As your IRB of record for the above referenced study, the Copernicus Group IRB board has reviewed your submission information. Enclosed is your approval notice. Be sure to carefully maintain the original documents so that copies may be made when necessary. As Principal Investigator, you agree to uphold your responsibility to protect the rights and welfare of your subject at all times while adhering to all applicable federal regulations governing the conduct of clinical research trials.

Copernicus Group IRB reserves the right to visit your research site at any time with appropriate prior notice.

We are also enclosing a Copernicus Group IRB Investigator Guidebook that details the IRB's expectations, procedures and contact information. Please carefully read this Guidebook and have your study staff do the same. CGIRB forms and additional information regarding the conduct of clinical trials are available on our web site: www.cgirb.com.

If you have any questions regarding the contents of this letter or your working relationship with Copernicus Group IRB, please do not hesitate to call us at 1-888-303-2224 or email us at irb@cgirb.com. To avoid delay in locating your records we ask that you refer to the IRB Tracking number located in the header of this letter.

We look forward to working with you.

Copernicus Group IRB

cc: Polly Armsby, Social and Scientific Systems (scan and e-mail)



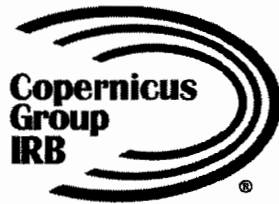
IRB APPROVAL DATED:
December 12, 2006
EXPIRATION DATE: December 11, 2007

Protocol #: 02-E-N271

Investigator: Dale P. Sandler PhD

Approval Includes:

NIEHS Sister Study Protocol dated 10/5/2006
IRB Memorandum Regarding Expansion of Recruitment to Puerto Rico
2006 Protocol Deviations
Sister Study Informed Consent (English & Spanish)
Recruitment Materials:
Sister Study DVDs (English & Spanish)
"Ask Me About the Sister Study" Buttons (English & Spanish)
"Ask Me About the Sister Study" Stickers (English & Spanish)
Sister Study Nail Files (English & Spanish)
Sister Study Fans (English & Spanish)
Sister Study Magnet
Sister Study Information card (business card size)
Sister Study Brochures:
General Study Brochure
A Special Invitation for Senior Women
A Special Invitation for African American Sister
A Special Invitation for Latina Sisters (Spanish & English)
A Special Invitation for Asian & Pacific Islander Sisters
Brochure Insert - Response Card
Sister Study Bookmark (English & Spanish)
Sister Study Flyers:
Half-page Flyer (English & Spanish)
Full Page Flyers:
General (English & Spanish)
A Special Invitation to Women Working in Trades and Industry (English & Spanish)
A Special Invitation to American Indian and Alaskan Native Women
A Special Invitation for Asian & Pacific Islander Sisters
Registry Recruitment Protocol and Materials
Screening and Enrollment Materials:
Web Screener
Web Screener Reminder Letter 1 & 2
Cold Call
Pregnancy Hold Lift Letter
Study Activity Delay Hold Lift Letter
Enrollment Completionq
Initial and Second Postcards
Sister Study Kit:
Letter and Graphics
1-Week to Kit Letter
Box Label (English & Spanish)
Kit Letter
How to Use Kit Instructions (English & Spanish)
Consent and Answers to Questions Folder
Consent Form (English & Spanish)
Frequently Asked Questions (English & Spanish)
Worksheets Folder
Life Events Worksheet (English & Spanish)
Medications Booklet (English & Spanish)
Questionnaires to Fill Out Folder
Family History Questionnaire (English & Spanish)
Contact Form (English & Spanish)
Personal Care Questionnaire (English & Spanish)
Diet Questionnaire (English & Spanish)
Toenail Collection Folder
Toenail Instructions (English & Spanish)
Dust Collection Folder
Dust Instructions (English & Spanish)
Urine Collection and Past 24 Hours Questionnaire Folder
Urine Instructions (English & Spanish)
Past 24 Hours Questionnaire (English & Spanish)
Fasting Instructions (English & Spanish)
Examiner Folder
Boold Instructions (English & Spanish)
Examiner Form (English & Spanish)
Blood Pressure Form (English & Spanish)
CATI Interview
Specimen/Self-Administered Questionnaire Collection
Scheduling Call
EMSI Sister Study Script
EMSI Appointment Card
Examiner Reminder Call Script
Examiner Checklist
Outstanding Items Letter
Results Handouts
Diet Report & Unanalysis Cover Letter
Urinalysis Results Handout - Negative
Urinalysis Results Handout - Positive
Urinalysis Results Handout - Strongly Positive
Diet Report
Diet Results - Variable text
Nutrition Fact Update Guidelines (English & Spanish)
Repeat Collection Marerials
Re-Draw Script
Repeat Part 24 Hours Questionnaire (English & Spanish)
Repeat Examiner Form



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Saliva Collection Cover Letter
Other Participant Communications:
Materials for Women Diagnosed with Breast Cancer
Diagnosis Card Cover
Diagnosis Card Message
Referral Card Insert
Package for Women Who Complete All Baseline Activities
Thank You Letter
Your Contact Info (English & Spanish)
Keep in Touch Magnet
Tracing and Non Response Letters
Non Response Letters 1, 2, 3, 4, 5
Tracing Letters 1, 2, 3
Follow Up and Retention:
Annual Follow-Up data Collection
Follow-Up Letter
Health Update Form
Contact Update Form
Sister Study Newsletter - 2006
Annual Update Phone Follow-Up Script - 2006
Biennial Follow-Up Data Collection
Biennial Health Questionnaire
Biennial Lifestyles Questionnaire
Behavioral and Psychological Health Questionnaire
Incident Breast Cancer Case Follow-Up
Case Follow-up Questionnaire
Cover Letter to Participant - Blood Draw
Consent for Additional Blood Draw
BCRA Participant Letter
Authorization Form -Pathology
Authorization Form -Records
Repeat Past 24 Hours Questionnaire
Repeat Examiner Form
BCRA Provider Letter
Medical Providers FAQ
Provider Report Form
Cohort Maintenance - 2006 New Year Card
Principal Investigator



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Investigator Address: Dale P. Sandler PhD

National Institute of Environmental Health Sciences (NIEHS)
111 T W Alexander Drive MSC A3-05
Research Triangle Park, NC 27709

Sponsor: NIEHS

CRO: Social and Scientific Systems

Protocol Title: The Sister Study: Environmental and Genetic Risk factors for Breast Cancer

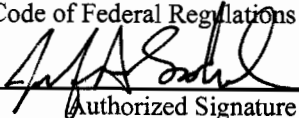
Approval is granted subject to the following considerations:

- Responsibilities of the Principal Investigator as found in the Investigator Guidebook
- In the event that non-English speaking subjects are recruited, a certified translation of the informed consent must be approved by the IRB before recruitment.
- If subjects who cannot read are recruited, there should be an impartial witness to attest to the adequacy of the consent process and to the subject's voluntary agreement to be in the study. This witness should also verify the subject's signature or mark on the consent form.
- Please note that if revisions are required for any approved item (particularly advertisements), they must be approved prior to use.
- If CGIRB has requested changes to your recruitment material, please forward a clean copy of the recruitment material, incorporating the changes noted. If the recruitment material is audio/visual, please provide an electronic copy via one of the following methods, email, CD or DVD for our files.
- If pediatric subjects are to be enrolled then they should be re-consented when they become of legal age.

IF YOU HAVE ANY QUESTIONS, CALL COPERNICUS GROUP IRB AT 1-888-303-2224

This signature certifies that the information contained in this IRB Approval Notice is true and correct as verified by the minutes and records of The Copernicus Group, Inc. It also certifies that The Copernicus Group, Inc. is in full compliance with FDA Code of Federal Regulations (21 CFR Parts 50, 56, 312, and 812 and 45 CFR) and ICH Guidelines.

Signature


Authorized Signature

Date 12/12/2006

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