SISOMB2012 ATTACHMENT 9: CGIRB CR

	Signature Page	
copernicus group independent review board	**Title**	SSS1-06-402_Sandler_Dale_P._Approvals_2012-09-27
	Summary	Sandler Dale P.

Signed By:	Reason:	Date/Time:
Melody Sawyer	Authorized Signature	September 28, 2012 9:43:00 AM EDT

September 28, 2012

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,

Enclosed please find an Approval Notice dated September 27, 2012 for the above-mentioned protocol.

This is to inform you that the Copernicus Group IRB has approved the above-referenced study for another year. Please continue to use the latest IRB approved Site-Specific Subject Information and Consent Form(s). Note that any changes in the study must be communicated to the Copernicus Group IRB.

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. Send faxes for this project to 1-919-654-7197.

Copernicus Group IRB

cc: Elizabeth Long O'Connell, Social And Scientific Systems (Email)
Polly Armsby, Social And Scientific Systems (Email)

IRB APPROVAL DATED:
September 27, 2012
STUDY EXPIRATION DATE: September 26, 2013

Protocol #: 02-E-N271
Investigator: Dale P. Sandler PhD
Approval Includes:
Re-Approval of Study

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 pediatric subjects are to be enrolled then they should be re-consented when they become of legal age.
- Please note that CGIRB requires the reporting of any unanticipated problems involving risks to subjects or others as soon as possible, but in all cases within 10 business days in accordance with the applicable regulatory standards and CGIRB requirements.

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 See appended electronic signature page IRB TRACKING # SSS1-06-402

Authorized Signature