copernicus group independent review board

31Aug2015

Dale P Sandler PhD
National Institute of Environmental Health Sciences
111 Tw Alexander Dr
Research Triangle Park NC 27709-0002

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

Dear Dr. Sandler,

Enclosed please find an Approval Notice dated 28Aug2015 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 Informed Consent Form(s). Please refer to Connexus® to access the latest version of your Informed Consent Form, if needed. All documents previously approved for the study are renewed with this re-approval. 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.

Sincerely,

Copernicus Group IRB

cc: Ms. Maisha Kudumu , Social And Scientific Systems (Email)

Copernicus Group IRB
One Triangle Drive Suite 100
Durham, NC 27713
Mailing Address:
P.O. Box 110605
Research Triangle Park, NC 27709

Experience and Innovation in Ethical Review ™

Telephone: 919-465-4310
Toll-Free: 888-303-2224
Fax: 919-465-4311
E-Mail: irb@cgirb.com
Web: www.cgirb.com

IRB APPROVAL DATED:
28Aug2015
STUDY END APPROVAL DATE:17Sep2016

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

The above listed item(s) are approved for use at your site(s) for the above referenced protocol.

Sponsor: NIEHS

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

Approval is granted subject to the following considerations:

- The Principal Investigator will meet his/her obligations as described in the Investigator Guidebook.
- The Principal Investigator must report any unanticipated problems involving risks to subjects or others as soon as possible, but in all cases within 5 business days in accordance with the applicable regulatory standards and CGIRB requirements.
- If subjects who are not able to consent for themselves are allowed in the study, a legally authorized representative must provide consent on the subject's behalf.
- If subjects who cannot read (for reasons of literacy or visual impairment) are allowed in the study, an impartial witness must sign the consent form to attest to the adequacy of the consent process and to the subject's voluntary agreement to be in the study.
- 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 pediatric subjects are allowed to be enrolled then they should be re-consented when they become of legal age.
- Please note that if revisions are required for any approved item (particularly advertisements), they must be approved by the IRB prior to use.

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

The information contained in this IRB Approval Notice is true and correct as verified by the minutes and records of The Copernicus Group, Inc. 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.

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