DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health
National Institute of
Environmental Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709
Website: www.niehs.nih.gov

Continuing Review Approval Letter

Date: September 2, 2009

From: David Resnik, JD, PhD, Chair, NIEHS IRB

To: Dale Sandler, PhD, Principal Investigator, NIEHS

Subject: Notification of Action on Continuing Review of Protocol Titled: The Sister Study: Environmental and Genetic Risk Factors for Breast Cancer (02-E-N271)

Expiration Date: **08/12/2010**

Risk Assessment: The research involves no more than minimal risk to subjects.

Benefit Assessment: No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge to further society's understanding of the disorder or condition under study.

Type of Review

☒ Full IRB Review Meeting on: 08/13/2009 ☐ Expedited Review on:

IRB Action

☒ Unconditionally Approved

According to Federal Regulation (45 CFR 46), a continuing review of research shall be conducted at intervals appropriate to the degree of risk, but not less than once per year. To achieve regulatory compliance, your complete continuing review packet must be submitted to the Office of Human Research Compliance continuing review June, 2010 for review at the July, 2010 NIEHS IRB meeting.

Changes in research activities during the approved IRB period shall not be initiated without prior IRB review and approval. Additionally, investigators must report to the IRB adverse events and protocol violations in accordance with procedures outlined in the protocol. Only consent forms with a valid approval date through 08/12/2010 may be presented to participants.

For further guidance, please contact the Office of Human Research Compliance via e-mail at: NIEHS Office of Human Research Compliance@niehs.nih.gov, call (919) 541-3852 or view the website at: http://sharepoint.niehs.nih.gov/ohrc/default.aspx

Sincerely,

David B. Resnik, JD, PhD
Chair, NIEHS IRB

Copy: OHRC File

CLINICAL RESEARCH PROTOCOL **CONTINUING REVIEW APPLICATION**	PROTOCOL NO. 02-E-N271	PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email): Dale P Sandler PhD

PROTOCOL TITLE:

Environmental and Genetic Risk Factors for Breast Cancer: The Sister Study

PROTOCOL STATUS:

- ☐ Renew -Recruitment of participants has not yet begun.
- ☒ Renew -Participants are currently being recruited or enrolled.
- ☐ Renew -No longer recruiting or enrolling participants, subject follow-up only.
- ☐ Renew -Participants have completed study; study and data analyses ongoing.
- ☐ Renew -Clinical Hold/Recruitment or enrollment of participants suspended.
- ☐ Terminate -Study closed. Participants have completed study. Recruitment and data analysis complete.

SUMMARY OF PROTOCOL ENROLLMENT (Aggregate): Only when the NIH is the coordinating site, provide totals and enrollment table for other site.

NIH Site	Other Sites	Total	
60,000		60,000	Accrual ceiling by IRB
6,860		6,860	New subjects accrued since last CR
50,266		50,266	Aggregate total accrued

Are you currently recruiting healthy volunteers? ☐ No ☒ Yes
Will the protocol involve adults unable to give informed consent? ☒ No ☐ Yes

Have analyses by sex /racial/ethnic subgroups been conducted for Phase 3 Clinical Trials as required? ☐ No ☐ Yes (answer a and b) ☒ N/A

a. Have analyses been reported? ☐ No (explain in narrative) ☐ Yes
b. Have significant differences been found? ☐ No ☐ Yes

Have any non-NIH investigators or sites been added since the last review?

- ☒ No
- ☐ Yes (Identify the persons or sites and describe the collaboration in the summary report)

WITH THIS REVIEW, I AM REQUESTING A CHANGE TO THE FOLLOWING:
*Include Name, Inst/Branch, Telephone, Address, e-mail. Check box if an NIH Employee and initial line. Attach sheet if necessary.

PRINCIPAL INVESTIGATOR:
Delete: _____
Add*: ☐ _____

EXTRAMURAL ADJUNCT PRINCIPAL INVESTIGATOR:
Delete: _____
Add: _____

MEDICAL ADVISORY INVESTIGATOR:
Delete: _____
Add*: _____

LEAD ASSOCIATE INVESTIGATOR:
Delete: _____
Add*: ☐ _____

RESEARCH CONTACT:
Delete: _____
Add*: ☐ _____

ASSOCIATE INVESTIGATOR(S):
Delete: _____
Add*: ☐ _____

IONIZING RADIATION USE (X-rays, e.g., CT, radioisotopes, e.g. PET, etc.) check all that apply:

- ☒ None
- ☐ Medically indicated
- ☐ Research indicated. Since the last review,
  - ☐ Research usage HAS NOT changed.
  - ☐ Research usage HAS changed. (Explain in summary report)

INVESTIGATIONAL NEW DRUG/DEVICE: ☒ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet.

FDA No. _____
Name: _____
Sponsor: _____
Who is the manufacturer of the above entity? _____

Does the protocol involve a Tech Transfer Agreement? ☒ No ☐ Yes

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?

- ☒ No
- ☐ Yes (Append a statement of disclosure)

Have there been any amendments since the last review?

- ☐ No
- ☒ Yes (Describe briefly in the attached narrative.)

Have there been any changes in the informed consent process or documentation since the last review?

- ☒ No
- ☐ Yes (Describe in Summary report)

Have there been any changes in the subject population, recruitment or selection criteria since the last review?

- ☒ No
- ☐ Yes (Explain changes in the attached narrative.)

Have any unexpected complications or side effects been noted since the last review?

- ☒ No
- ☐ Yes (Identify and explain in the attached narrative.)

Have any subjects withdrawn from this study since the last IRB approval?

- ☐ No
- ☒ Yes (Discuss in the attached narrative.)

Has any information appeared in the literature, or evolved from this or similar research, that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?

- ☒ No
- ☐ Yes (Discuss in the attached narrative.)

Has the NIH IRP COI Guide been distributed to new NIH investigators?
☐ No ☐ Yes ☒ N/A

Has the NIH IRP COI Guide been distributed to new Non-NIH investigators?
☐ No ☐ Yes ☒ N/A

CONFLICTS OF INTEREST REVIEW?
Date submitted to IC DEC: 7/30/09 Date cleared by IC DEC: 7/10/09

SIGNATURE	Dale P Sandler Principal Investigator	Dale P Sandler PhD Print/Type Name	Date 7-28-09	Send to Accountable Investigator
RECOMMENDATION	Dale P Sandler Accountable Investigator	Dale P Sandler PhD Print/Type Name	Date 7-28-09	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	Branch Chief/CC Dept. Head of Accountable Investigator	Jack Lazo Print/Type Name	Date 7/28/9	Send to Clinical Director
APPROVALS	Clinical Director	DARRYL ZELDIN MD Print/Type Name	Date 07/28/09	Send to Chair, Institutional Review Board
	Chair, Institutional Review Board	David B Resnik Print/Type Name	Date 9/02/09 Protocol & Consent Approved Effective	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	Protocol Specialist	Date 09/15/09		