CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION	PROTOCOL NO. 11-E-N076	PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email): Dale P Sandler, Ph.D., NIEHS/EB, 919-541-4668, sandler@niehs.nih.gov

PROTOCOL TITLE: GuLF Study: Gulf Long-Term Follow-Up 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	
0	55000	55000	Accrual ceiling by IRB
0	6084	6084	New subjects accrued since last CR
0	32812	32812	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: _____ Date cleared by IC DEC: _____

SIGNATURE	Dale P Sandler Principal Investigator	Dale P Sandler, Ph.D. Print/Type Name	Date e-Signed on 8/7/13 6:30 PM	Send to Accountable Investigator
RECOMMENDATION	Dale P Sandler Accountable Investigator	Dale P Sandler, Ph.D. Print/Type Name	Date e-Signed on 8/7/13 6:31 PM	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	Dale P Sandler Br Chief/CC Dept. Head of Acct. Invest	Dale P Sandler, Ph.D. Print/Type Name	Date e-Signed on 8/7/13 6:31 PM	Send to Clinical Director
APPROVALS	Stavros Garantziotis Clinical Director	Stavros Garantziotis, M.D. Print/Type Name	Date e-Signed on 8/14/13 4:38 PM	Send to Chair, Institutional Review Board
	David B Resnik Chair, For Institutional Review Board	David B Resnik, J.D., Ph.D. Print/Type Name	Date e-Signed on 9/16/13 2:02 PM	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	N. Almodovar Protocol Specialist	Date 9/17/13	Protocol & Consent Approved Effective	