

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: \_\_\_\_\_

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