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
http://sharepoint.niehs.nih.gov/ohrc/default.aspx

Date: July 03, 2013
To: NIEHS IRB Chair, through the Office of Human Research Compliance
From: Chief, Epidemiology Branch and PI, the GuLF STUDY
Subject: Expedited Amendment to Protocol # 11-E-NO7 titled "The Gulf Long-term Follow-up Study"

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from members of the IRB in accordance with the requirements set forth in 45 CFR 46.110. Additional information on determining the appropriate level of review for a submission can be found at http://ohsr.od.nih.gov/irb/Attachments/Chapter7.htm.

Note: *If an NIH investigator is added to the protocol, attach a signed/cleared Personal Financial Holding Clearance form along with an e-mail from the new investigator stating they are aware they are being added to the protocol.*

Expedited Amendment Summary and Justification:

We request expedited review and approval of an addendum to the GuLF STUDY protocol to fully describe our plans for carrying out the Biomedical Surveillance Sub-cohort clinical examination referenced in the current study protocol. A subset of 6,000 cohort members will be invited to take part in the exam, which includes repeated measures from the baseline home visits and comprehensive neurobehavioral, mental health, and pulmonary function testing. We believe that the exam presents minimal risk to participants and may, in fact, present less risk than the home exam because it is being carried out in a clinical setting under the direction of physicians. The specific details of the updates to the protocol and the file names for the associated attachments are detailed below.

I. Protocol and Questionnaires

{Attachment: GuLF_Study_Protocol_V19.0_07022013_CLEAN.docx; GuLF_Study_Protocol_V19.0_07022013_TRACKED.docx; Clinical Exam Questionnaires _V1.0_07022013_CLEAN.docx; Mental Health Questionnaire for the Clinical Exam_V1.0_07022013_ CLEAN.docx}

About 6,000 cohort members will be eligible to take part in the clinical examination component of the study, and we expect that about 4,000 (67%) will complete the exam. The exams will be carried out by collaborators from the University of South Alabama (USA) and Louisiana State University (LSU) Health Sciences Center. The eligible population includes all members of the Biomedical Surveillance Sub-cohort (N~4,000) and a "supplemental" sample of members of the Active Follow-Up Sub-cohort (N~2,000). The supplemental sample will be selected on based on potential exposures and baseline measures of mental health status and pulmonary function.

The exam will take approximately 4 hours to complete, and participants will receive $150.00 for their time and effort. Exam components include anthropometric and clinical measurements, biological sample collection, neurobehavioral and lung function testing, a comprehensive mental health assessment, and questionnaire about health and lifestyle. Participants will receive the results of clinically relevant exam findings at the time of the visit and will receive health care referrals, if requested. A subset of participants (N~1,000) will be asked to collect serial saliva samples at home following the exam, and they will receive an additional $20.00 for returning the samples.

III. Invitational and Pre-visit Material

{Clinic_Exam_Lead_Letter_V1.0_07022013.docx; Calling_Scripts_Clinic_Exam_V1.0_07022013.docx; GuLF_STUDY_Clinic_Exam_Confirmation_Letter_V1.0_07022013.docx; Clinic Visit_Frequently_Asked_Questions_V1.0_07022013.docx; Clinic_Visit_Instructions_V1.0_07022013.docx}

Eligible cohort members will receive an invitation mailing that encourages them to take part in the exam. Clinical staff will actively contact participants to schedule visits. Standardized scripts will be used to guide scheduling calls. After visits are scheduled, participants will receive a visit confirmation package, which includes a cover memo, a summary of the informed consent form, answers to frequently asked questions, information on how to prepare for their visit, and directions to the clinic.

II. Consent(s)

{Consent_Form_Summary_Sheet_V1.0_07022013.docx; GuLF_Informed_Consent_Booklet_Clinic Exam_V_1.0_07022013.docx}

The one-page consent form summary that is include with the visit confirmation package briefly covers key topics in the informed consent form, such as exam procedures, benefits, risks, remuneration, and privacy and confidentiality. At the time of the examination, study staff will review the Informed Consent Form with participants, address any questions or concerns, and obtained written informed consent before carrying out any study procedures.

IV. Other

{Blood_Pressure_Results_V1.0_07022013.docx; BMI_Results_V1.0_07022013.docx; Cholesterol_Results_V1.0_07022013.docx; Hemoglobin_A1c_Results_V1.0_07022013.docx; HR_Results_V1.0_07022013.docx; PFT_Results_V1.0_07022013.docx; Clinic_Visit_Gift_Card_Receipt_V1.0_07022013.docx; Saliva_General_Instructions_V1.0_07022013.docx; Saliva_Collection_Instructions_V1.0_07022013.docx; Saliva_Mail_Instructions_V1.0_07022013.docx; Saliva_Collection_Log_V1.0_07022013.pdf }

Participants will receive results of clinically relevant findings during their exam, including blood pressure and heart rate, body mass index, cholesterol levels, hemoglobin A1c, and pulmonary function testing. Results will be provided on handouts that include standardized clinical interpretations and advice for seeking care.

A subset of ~1,000 participants will be asked to provide serial saliva samples for the measurement of salivary cortisol. Five salvia samples will be collected on two different days during a one week period using an in-home procedure. Participants will complete a collection log that details their activities at the time that the sample was collected.

Participants will receive a gift card for their time and effort following the completion of their clinic examination. A gift card receipt will be signed by the study staff and the participant to document that they have received their remuneration. The gift card receipt will be maintained with the study files.

Dale P. Sandler

Principal Investigator, NIEHS

I authorize the above changes to my study and have included updated edited and clean versions of all revised documents as attachments for submission via my NIH e-mail account to the NIEHS Office of Human Research Compliance.

For Approving Official Use Only:

The attached expedited amendment request is a minor change in the research that does not increase risks to subjects or reduce potential benefits and falls within the OHRP Categories of Research that May be Reviewed by the IRB through an expedited review procedure. Approval is hereby granted.

N. Almodovar	7/12/13	Y
Protocol Specialist Office of Protocol Services	Date	Amendment Letter

Protocol eSign History

Protocol Number: 11-E-N076 Review: Amendment 07/02/2013 (25)

Date/Time	User	Type	Action
07/02/2013 6:25 PM	Dale Sandler	Electronic signature access	eSignature Verified Principal Investigator
07/02/2013 6:25 PM	Dale Sandler	Electronic signature access	eSignature Verified Accountable Investigator
07/02/2013 6:25 PM	Dale Sandler	Electronic signature access	eSignature Verified Branch Chief
07/02/2013 6:34 PM	Dale Sandler	Electronic signature access	eSignature Verified Accountable Investigator
07/02/2013 6:34 PM	Dale Sandler	Electronic signature access	eSignature Verified Branch Chief
07/03/2013 2:00 PM	Frederick Miller	Electronic signature access	eSignature Verified Clinical Director
07/08/2013 12:49 PM	David Resnik	Electronic signature access	eSignature Verified IRB Chair