



Date: April 18, 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“

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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.*

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**Expedited Amendment Summary and Justification:**

We request expedited review and approval of the following updates to the GuLF STUDY protocol and study documents:

- 1.) Additional details about our plans for carrying out the first follow-up telephone interview;
- 2.) The addition of a supplemental mental health questionnaire for ~4,600 participants;
- 3.) \$500.00 gift card drawings for participants who complete the follow-up telephone interview;
- 4.) \$500.00 gift card drawings for early responders who complete the interview within three weeks of their first request for participation;
- 5.) An invitational mailing to be sent to participants in advance of the follow-up telephone interview;
- 6.) The first installment of the GuLF STUDY Newsletter; and
- 7.) A waiver form to use a participant photo and quote in the GuLF STUDY Newsletter.

The specific details of the updates to the protocol and the file names for the associated attachments are detailed below.

**I. Protocol**

*{Attachment: GuLF\_Study\_Protocol\_V18.0\_04182013\_CLEAN.docx;  
GuLF\_Study\_Protocol\_V18.0\_04182013\_TRACKED.docx }*

We propose a revision to the protocol to more fully describe our plans for carrying out the first follow-up telephone questionnaire. Interviews will be conducted with ~20,000 participants, including those in the Active Follow-up Sub-cohort who completed their home visit examination (N=~11,000) and a random sample from the Full Cohort (N=~9,000). The interview will take 30 minutes to complete and will be administered by trained interviewers via computer assisted telephone interviewing software.

As part of a collaboration with SAMHSA to address ongoing concerns about the impacts of the Deepwater Horizon disaster on mental health, we propose to invite ~4,600 participants to complete an additional questionnaire module on potential mental health issues. The module will be administered in four waves, beginning at the time of the first follow-up telephone interview, and then again at 6, 12, and 24 months later. The additional module will assess changes in mental health status over time and will help us understand the impact of extended unemployment, other chronic or new stressors, and the impact of social and community support on mental health trajectories. Participants selected for the additional questions will include a sample of ~3,600 participants with potential mental health issues at baseline, as well as ~1,000 participants who did not indicate any potential mental health issues. The additional module will take approximately 20 minutes to complete and participants will receive \$10.00 upon completion of each interview wave.

In an effort to encourage participation in the follow-up telephone interview, we propose to hold a series of drawings for \$500.00 gift cards for participants who complete the interview. One winner will be selected after every 500 interviews are completed. We also plan to include an additional drawing for early responders who complete the interview within three weeks of the release of their invitational mailing. One \$500 gift card will be awarded after every 500 early responders complete their interview.

### **III. Other**

#### Follow-Up Telephone Questionnaire

*{Attachments: GuLF STUDY Follow-Up Telephone Questionnaire V1.0\_04082013.docx}*

The follow-up telephone questionnaire will collect updated data on participants since the time of completing their last telephone or home visit questionnaire. Information collected includes updated contact and demographic information, additional oil spill clean-up tasks completed, health and mental health status, and lifestyle and residential history. Questionnaire items were largely drawn from the Telephone Enrollment and Baseline Home Visit questionnaires, although some new items from standardized questionnaires were added in some sections to expand our understanding of the health effects of the spill. The interview will take approximately 30 minutes to complete and will be administered in English and Spanish. Spanish translations will be submitted for approval after we have some early experience administering the follow-up questionnaire in English.

#### Mental Health Add-On Survey

*{Attachments: Supplemental Mental Health Questionnaire\_V1.0\_04082013.docx}*

In collaboration with SAMHSA, a supplemental survey module will be administered to a subset of participants and is designed to characterize disaster-related stress in the cohort in order to provide more comprehensive estimates of mental health needs in the community, evaluate mental health trajectories, assess the impact of prior and ongoing stressors, quantify interactions with mental health care providers, and evaluate the impact of these interactions on resilience, stress, and coping. The module will collect specific data on mental health measures such as social support, depression, resiliency, and other traumatic life events using standardized scales.

#### Invitational Lead Letter and Newsletter

*{Attachments: GuLF STUDY Follow-up Lead Letter\_V1.0\_04182013.docx; GuLF STUDY Newsletter Issue 1 V1.0\_04182013.pdf; GuLF Release Form 20130416 V1.0.doc}*

Participants will be mailed an invitational letter in advance on the follow-up interview that explains what they will be asked to do and to encourage them to participate. We also plan to mail or email the first issue of the GuLF STUDY Newsletter around the time that telephone follow-up begins. The newsletter will provide study updates on enrollment and information about upcoming study events. The newsletter will include a photo of a current participant and a quote explaining why the participant joined the study. The participant will be asked to read and sign a release form giving us permission to use their photo and statement in the newsletter. The participant will be provided with a copy of the waiver.

*Note: The photo and the quote in the attached Newsletter are not from a real GULF STUDY participant.*

#### *Summary*

We have included a tracked changes version of the protocol for your review. In addition, the questionnaires, lead letter, newsletter, and release form are included for your review. The specific revisions are detailed in the tables below.

**GuLF STUDY Summary of Changes**  
**04/18/13**

**Table 1. Protocol**

Page #	Section	Description of change
All	Throughout	<ul style="list-style-type: none"> <li>Updated version number and date in footer</li> </ul>
3-5	Table of Contents	<ul style="list-style-type: none"> <li>Updated page numbers</li> </ul>
57	2.13.1 Telephone Questionnaires	<ul style="list-style-type: none"> <li>Section updated to include additional details for the first telephone follow-up interview and a supplemental mental health module for a sub-group of participants</li> </ul>
60-61	2.15 Remuneration	<ul style="list-style-type: none"> <li>Reorganized section to include additional \$500.00 gift card drawings for participants who complete the follow-up telephone interview</li> <li>Added \$10.00 in remuneration for participants who are selected for and enroll in the additional mental health module(s)</li> </ul>
86	9.2 Informed Consent Process	<ul style="list-style-type: none"> <li>Added procedure for consent to the follow-up telephone interview</li> </ul>

*Das P. Sandhu*

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.

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***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  
Protocol Specialist  
Office of Protocol Services

4/25/13  
Date

X  
Amendment  
Letter

## Protocol eSign History

Protocol Number: 11-E-N076

Review: Amendment 04/18/2013 (24)

Date/Time	User	Type	Action
04/18/2013 3:26 PM	Dale Sandler	Electronic signature access	eSignature Verified Principal Investigator
04/18/2013 3:26 PM	Dale Sandler	Electronic signature access	eSignature Verified Accountable Investigator
04/18/2013 3:26 PM	Dale Sandler	Electronic signature access	eSignature Verified Branch Chief
04/18/2013 3:26 PM	Dale Sandler	Electronic signature access	eSignature Verified Accountable Investigator
04/18/2013 3:26 PM	Dale Sandler	Electronic signature access	eSignature Verified Branch Chief
04/19/2013 5:34 PM	Stavros Garantziotis	Electronic signature access	eSignature Verified Clinical Director
04/19/2013 10:56 PM	David Resnik	Electronic signature access	eSignature Verified IRB Chair