



Date: August 24, 2012
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 of the proposed annual request for updated contact information for participants who have completed the telephone enrollment interview. Requests for updated contact information will be sent to participants by email and USPS mail and will include a link to the Update Contact Information page on the study website. Participants will be able to view and confirm their information by entering a combination of their last name, date of birth, and last four of their SSN or their unique PIN number on the secure and encrypted site. Participants may also call the study hotline to confirm or update their information. As study findings and updates become available, the email / letter requests will include an annual newsletter with study information. The newsletter will be submitted to the IRB prior to distribution. The email / letter to participants and a detailed description of the annual re-contact procedures are attached (*GuLF STUDY Annual Re-contact Request v1.0 080242012; GuLF STUDY Annual Recontact Plan v1.0 08242012.docx*).

As of August 21, 2012, 27,588 persons have enrolled in the Full Cohort and almost 18,000 are in-progress and pending final disposition; over 4,000 of these participants speak either Spanish or Vietnamese. In addition, target efforts are underway to identify and recruit rig workers who responded to the clean-up effort in the area of the well-head. Since rig-workers reached the worksite through alternate means, many were not included in the initial worker lists we obtained from BP and its contractors. We only recently learned of this omission and were able to obtain information needed to recruit them in the past few months. As described in the Protocol, we intentionally started enrollment at a slower pace to ensure that data collection efforts work as planned, followed by a ramp-up of enrollment efforts in the fall of 2011. Furthermore, a large proportion of the contact information for the participants is incomplete or out-of-date resulting in increased efforts to trace these individuals for additional contact information and recruitment attempts. Although we are now enrolling at a steady pace and our numbers have increased substantially since last review, the slower start and extensive tracing effort has left us behind where we had hoped to be at this time. Thus, we propose extending the accrual period from 18 to 21 months for Full Cohort Enrollment and extending the timeframe for completion of home visits for the Active Follow-up Sub-cohort from 18 to 24 months. This change has the support of our Scientific Advisory Board and will allow for more pending cases to be finalized and increase overall enrollment. Further, it will allow us sufficient time to enroll Spanish and Vietnamese participants and the rig workers, who are currently under-represented.

I. Protocol

{Attachment: *GuLF STUDY Protocol V12.0 08242012 TRACKED.docx, GuLF STUDY Protocol V12.0 08432012 CLEAN.docx*}

Summary of Changes

Page #	Section	Description of change
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All	Throughout	<ul style="list-style-type: none"> Updated version number and date in footer
8	Protocol Summary	<ul style="list-style-type: none"> Changed accrual period to end 12/2012
10	Précis	<ul style="list-style-type: none"> Changed 18 to 21 months
24	2.3.1 Recruitment Database	<ul style="list-style-type: none"> Changed 18 to 21 months for Full Cohort Changed 18 to 24 months for home visits
58	2.14.1 Annual Update of Contact Information	<ul style="list-style-type: none"> Revised plans for annual updates of participant contact information

Dan P. Sandler

GuLF STUDY 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.

Dawn Roy
 Protocol Specialist
 Office of Protocol Services

9/14/12 N
 Date Amendment
 Letter

Protocol eSign History

Protocol Number: 11-E-N076

Review: Amendment 08/27/2012 (14)

Date/Time	User	Type	Action
08/27/2012 9:13 PM	Dale Sandler	Electronic signature access	eSignature Verified Principal Investigator
08/27/2012 9:13 PM	Dale Sandler	Electronic signature access	eSignature Verified Accountable Investigator
08/27/2012 9:13 PM	Dale Sandler	Electronic signature access	eSignature Verified Branch Chief
08/28/2012 5:42 PM	Dale Sandler	Electronic signature access	eSignature Verified Accountable Investigator
08/28/2012 5:42 PM	Dale Sandler	Electronic signature access	eSignature Verified Branch Chief
08/30/2012 3:35 PM	Frederick Miller	Electronic signature access	eSignature Verified Clinical Director
08/30/2012 4:37 PM	David Resnik	Electronic signature access	eSignature Verified IRB Chair