



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"

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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.

Expedited Amendment Summary and Justification:

We request expedited review and approval of introduction scripts for the previously approved Supplemental Mental Health Questionnaire that will be administered to ~4,600 participants at the end of their follow-up telephone interview. The scripts inform the participant that they are eligible to complete the additional survey, will be invited to complete subsequent interviews, and that they will receive a \$10.00 for their additional time upon completion of these questions. A thank you letter and the gift card will be mailed to the participants within 2 weeks of completing the interview.

Associated Files:

SAMHSA_Mental_Health_Telephone_Scripts_V1.0_07022013
GuLF_STUDY_SAMHSA_Telephone_Thank_You_Letter_V1.0_07022013

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.

<u>N. Almodovar</u>	<u>7/15/13</u>	<u>Z</u>
Protocol Specialist	Date	Amendment
Office of Protocol Services		Letter

Protocol eSign History

Protocol Number: 11-E-N076

Review: Amendment 07/02/2013 (26)

Date/Time	User	Type	Action
07/02/2013 6:33 PM	Dale Sandler	Electronic signature access	eSignature Verified Principal Investigator
07/02/2013 6:33 PM	Dale Sandler	Electronic signature access	eSignature Verified Accountable Investigator
07/02/2013 6:33 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