

1. What is the purpose of the GuLF STUDY Clinical Exam?

The purpose of the clinical exam is to learn more about possible health effects of the oil spill in the Gulf of Mexico. The study exam will include comprehensive tests of lung and nervous system function, evaluation of mental health symptoms, and screening for diabetes and cholesterol.

2. Who is conducting the exam?

The National Institute of Environmental Health Sciences (NIEHS) designed and leads all aspects the GuLF STUDY. Social & Scientific Systems, Inc. (SSS), a professional research firm, and their partners are helping NIEHS conduct the exams. The clinical examinations will be carried out by the University of South Alabama (USA) and Louisiana State University (LSU) Health Sciences Center. Social & Scientific Systems trained, equipped, and manages all participating medical centers. All of these partners follow guidelines and procedures approved by the NIH Office of Human Subjects Research. This office exists to protect people in research studies.

3. Who is eligible for the exam?

You are eligible for the exam if you completed a GuLF STUDY home visit. You are eligible whether you worked on the spill or not and whether you are feeling sick or well.

4. What will I be asked to do?

- Provide blood, hair, toenail, urine, and possibly saliva samples
- Have your vital signs and body measurements taken
- Complete lung function tests
- Complete tests of nervous system function
- Complete a questionnaire about your health

5. Will I receive compensation for completing the exam?

You will receive a \$100 gift card for the time and effort required for the clinical exam. You will also be reimbursed for your travel expenses based on your distance from the clinic. You will receive your gift card when you complete your exam. Participants who provide saliva samples will receive an additional \$40 gift card. There is no cost associated with accepting a gift card.

6. What if I can't complete a full exam?

If special circumstances prevent you from completing the entire exam you may possibly be asked to complete a shorter 2-hour version of the exam. If you are eligible for and complete the short version, you will receive a \$50 gift card for the time and effort involved.

7. What tests will be done with my samples?

All of your samples will be frozen and stored in a secure laboratory. At a later date, we will use your samples for research. We will look for signs of oil exposure and related health effects. We will test samples for a variety of chemicals, hormones, markers of biological changes, and environmental agents. We will also study effects on genes and if genetic factors interact with chemical exposures to increase or decrease the chances of becoming sick. All research tests will not be done on all participants. We will not test for illegal drugs.

8. Will I receive the results of my blood tests and other study procedures?

You will receive results from some clinic laboratory tests and procedures at the end of your visit. We will report results from tests that may be clinically relevant such as blood pressure, body mass index, lung function, and diabetes and cholesterol screening. We will let you know if we think you should share your results with a doctor or clinic. Results from tests done in research laboratories will not be shared because their meaning to your health will not be clear.

Results will not be shared with your employer, health insurance company, or health care provider unless you ask us to in writing. Privacy rules strictly prohibit sharing information about study participants with these groups. However, you are allowed to share information with your employers and insurance provider. If an insurer or employer learns from you that you are in the study and you consent in writing to have the information shared, we will give out the information.

9. What should I do if I have questions about my exam results?

You should discuss your clinical test results with your doctor. If you do not have a regular doctor, we will provide a referral to a local health care provider. We will be happy to answer general questions about the tests. We will not provide medical care as part of this study. Your doctor will be in the best position to know what is right for you.

10. How will you protect my privacy?

We will make every effort to protect your privacy and keep your data confidential. People in NIH studies are not named in reports or presentations. Furthermore, a law called The Federal Privacy Act protects your information. We also have a Federal Research Certificate of Confidentiality for this study which further helps us protect your privacy. We will label the information from this exam with a special code number instead of your name so you will not be identified. Only authorized staff will see your private information.

11. What should I do if...

- **I want to find out if the exam is legitimate?** You may contact the Public Affairs/Communications Office at the NIEHS at 1-919-541-0073. You may also call the NIEHS Office of Human Research Compliance, at 1-919-541-3852.
- **I have questions about the exam or need to reschedule my appointment?** If you have questions about the exam, you may call the study clinic at 1-855-NIH-GULF (1-855-644-4853), or visit the study website at www.gulfstudy.nih.gov.
- **I have a problem or complaint about the clinic visit?** Please call the GuLF STUDY toll-free number, 1-855-NIH-GULF (1-855-644-4853), as soon as possible. Tell us about the problem and the date and time that it occurred. We will relay your concern to the investigators and our study staff. We will take any action that is necessary.