

Appendix H: Frequently Asked Questions



A health study for oil spill clean-up workers and volunteers

ANSWERS TO YOUR QUESTIONS

What is the GuLF Study about?

The GuLF Study is the largest health study that has ever been conducted among oil spill clean-up workers and volunteers. The study will learn about potential health effects of the Deepwater Horizon oil spill in the Gulf of Mexico. The study will enroll and follow 55,000 people. The study will include those who did clean-up work and others. About half of the people in the study will have a home visit to collect samples (including blood, urine, house dust) and carry out some clinical tests such as measuring blood pressure or lung function. This group will get health questionnaires every two years. Others will be followed through state and national health records like cancer registries.

Who is running the study?

Researchers at the National Institute of Environmental Health Sciences (NIEHS) are running the study. NIEHS is one of the National Institutes of Health, which is part of the Department of Health and Human Services. The website for the NIEHS is <https://www.niehs.nih.gov>. Dr. Dale Sandler, Chief of the NIEHS Epidemiology Branch, is the study's principal investigator.

Who is enrolling participants and collecting data for NIEHS?

SRA International, a professional company that specializes in health research, works closely with the NIEHS to recruit and enroll people in the study. They collect data and manage the day-to-day activities of the study. More information about SRA can be found at <http://www.sra.com>.

Is BP involved with the study in any way?

BP has donated money to the National Institutes of Health to fund health research related to the oil spill. Some of the money that BP donated will be used for the Gulf Study. But, most of the money for the study comes from the NIH directly. BP was not

involved in the design of the study. They will not play any role in carrying out the study. They will not analyze study data or influence how we interpret results.

Why is the GuLF Study important? What will it tell us?

More than 150,000 people did work related to clean-up of the oil spill in the Gulf of Mexico. Some had potential exposure to oil and other chemicals. By comparing health among all types of workers, we will learn about the potential risks from different types of clean-up activities. Some clean-up workers live in the area most directly affected by the oil spill and others live further away. Therefore, this study can also learn how stress and job loss because of the oil spill can affect health, including mental health. The findings from the study may influence long-term public health responses in Gulf communities or responses to other oil spills in the future.

Why study people who were not directly involved in clean-up activities?

By comparing workers doing specific clean up jobs to others who did not do those jobs, we can learn if health problems are occurring at a higher rate than expected among some groups of workers. If health problems occur more frequently among workers than the comparison group, researchers may conclude that the higher rate of illness is associated with oil and/or chemical exposures. That is because those exposures are the main differences between the groups.

Why was I contacted about the study? How did you get my name?

The NIEHS worked with other federal agencies, BP and its contractors, local government agencies, and community groups to develop a combined list of people eligible for this study. You have been contacted because we believe that you may be eligible to participate in the study, either because you worked directly in oil spill clean-up or because you had some other link to the oil spill.

Why are you concerned about health effects if workers had safety training and used protective gear?

Even workers who received training and tried to follow all the guidelines given to them may have had oil spill exposures. Heat and humidity made it hard to follow all of the guidelines. Safety procedures often reduce, but do not fully eliminate, certain exposures. The training and safety procedures were based on what was known at the time of the spill. But there have been few studies about the potential risks of oil spill clean-up. The size of this oil spill was bigger than any other. The oil traveled through lots of water before reaching the surface or the shore. This means that it was hard to know what to expect from research on other spills. It is very important to study the health of people who did clean-up. This will help identify and concerns for people who were exposed to the oil. It will help officials know what to do if there is another spill. It will hopefully lead to even better safety procedures the next time.

Will this study identify all diseases that may be associated with the spill?

The goal of this study is to identify diseases related to oil spill clean-up activities. This study will look at a wide range of diseases. We will follow workers for a long time so that we have a chance of finding out about diseases that take many years to develop. The study is large enough to identify many diseases, even ones that are less common. But it may not be possible to identify diseases that are very rare.

Why would I want to participate in this research study?

Most people who participate in research hope that it will produce information that will benefit themselves or others. Since no treatment is offered in this study, there are few risks or direct benefits to people in the study. Most people who participate in a study like this want to help other people. In this case, people in the study may want to help public health officials and health care providers better understand the potential health impacts of the oil spill on clean-up workers and local communities. They may want to help researchers and officials plan for how to respond if there are other large oil spills in the future.

Who makes sure this study is safe and scientifically sound?

Research funded by the Federal Government is carefully reviewed and monitored. This study has been reviewed by the Institute of Medicine (see <https://www.iom.edu>), an independent, non-profit group that works outside the government. This group gives unbiased and authoritative advice to decision makers and the public. The NIEHS hosted web-based meetings to gather feedback about the study from community groups, health care providers, public health officials, universities, and environmental groups. Individual meetings have also been held with many of these groups. The study was reviewed by representatives from multiple Federal Agencies and by university researchers in a process known as "Scientific Peer Review". Finally, the Institutional Review Board (IRB) of the NIEHS has reviewed and approved this study. The IRB is a diverse group that includes experts in the areas of ethics, law, medicine, and science. The input received from the overall review process has been used to improve the study.

How will I find out about study results?

Newsletters describing the progress and findings of the study will be mailed to people in the study every year. These reports will be posted on the study website. Results of the study will be reported in journals that are read by physicians, public health professionals, and scientists. Local, state, and national media groups will also be informed of study findings. We will hold community meetings to report results and send newsletters and reports from the study to interested groups.

What tests will be done with my samples?

All of your samples will be frozen and stored indefinitely 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 your 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.*

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

You will receive a report with results from measurements of your blood pressure, body mass index, lung function (if tested), complete blood count (if measured), and urine glucose (sugar) level. The report will be mailed to you within 3 to 4 weeks of your home visit. The report will include an explanation of what each test result means. If one of these results suggests you should see a doctor right away, we will tell you during the home visit or call you as soon as we get the results. The results will be from screening tests and should not be considered a medical diagnosis. We will let you know whether we think you should see a doctor based on the results. If you do not have a regular doctor, you may call the study center toll-free at 1-855-NIH-GULF (1-855-644-4853) to receive a referral to a local health care provider. We will not provide medical care as part of this study.

Will I receive any other clinically important results?

At this time, the exact number and specific types of tests we will do is not known. Although research tests of samples may reveal clinically useful information, it may be many years before your samples are analyzed. The tests we do for research may not be done in a certified clinical laboratory. Therefore, you should continue to visit your doctor for routine health care. If we discover something that could be clinically useful, we will send you results from tests done in a certified laboratory. If it is not possible to send results from a certified laboratory, we will send you a summary report of your findings that you can share with your doctor. Your doctor can help you decide if further actions or tests are needed.

What should I do if I have questions about my study results?

You should discuss your test results with your doctor. If you do not have a regular doctor, you may call the study center at 1-855-NIH-GULF (1-855-644-4853) to receive a referral to a local health care provider. We will be happy to answer general questions about the tests and what results could mean. You can call the study center with questions. 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.

Why do you need my Social Security number?

In order to accurately link to outside records containing information on deaths, cancer, and other diseases, we will ask you to share your Social Security number. Although you will have given other identifying information such as your name and date of birth, especially for common names, the Social Security number is the only factor that is unique to you and will allow us to make sure we get the correct information about changes in your health. We will store your Social Security number in a separate secure

file and will not share it with others. If you are still reluctant to share your Social Security number, we will ask you to provide the last 4 digits. This will help match to the correct records even though it does not uniquely identify you.

Why do you need identifying information, like my address, phone number, and date of birth?

During our initial telephone interview, we ask for your address, phone number, and date of birth to verify that we have contacted the right person for the interview. Some participants will be invited to take part in additional study activities after the initial telephone interview, such as home visits, follow-up telephone interviews, and clinical visits. We need contact information to reach participants who take part in those future activities. We also want to send all participants an annual newsletter to keep them updated about the study.

Will you share my information with my employer or insurance provider?

We will not give study information to employers or insurance providers. 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 employers 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. You and your family should actively protect your own privacy.

Why do I have to provide the names and telephone numbers of other contacts?

Since this is a long-term study, people in the study may move or change their telephone number and forget to tell us. We want to make sure we will be able to reach you in future years. If we have trouble reaching you, we will call the contacts you've provided to find out where we can reach you. Please select people who will always know where you are in case you move.

What Should I Do If...?

What should I do if I want to find out if the study is legitimate?

You may contact the Public Affairs/Communications Office at the NIEHS at 1-919-541-0073.

What should I do if I have questions about the study?

If you have questions about the study, you may call the Gulf Study toll-free number, 1-855-NIH-GULF (1-855-644-4853), and ask our staff any questions that you may have. You may also visit the study website at www.nihgulfstudy.org.

What should I do if I do not want to participate?

If you decide that you do not want to be contacted about the study, please call the Gulf Study toll-free number, 1-855-NIH-GULF (1-855-644-4853), as soon as possible. Tell us your name and let us know that you do not want us to call you. .

What should I do if I decide to participate and change my mind later?

You may withdraw from the study at any time. If you change your mind after you enroll, please call the Gulf Study toll-free number, 1-855-NIH-GULF (1-855-644-4853), as soon as possible. Tell us that you no longer want to be in the study.

What if I need to change the time of my home visit or forget the appointment?

Please call the Gulf Study toll-free number, 1-855-NIH-GULF (1-855-644-4853), as soon as possible. Tell us the date and time of your original appointment so that we can reschedule the visit.

What if I have a problem or complaint about the telephone interview or in-home 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.