

Appendix D: Informed Consent Form



OMB#0925-XXX
EXP:xx/xxxx

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

INFORMED CONSENT FORM For Active Follow-up Study

GuLF Study Informed Consent Form

Title of Study: Gulf Long-term Follow-up of Clean-up Workers Study

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You are being asked to be in a research study on possible health effects of the recent oil spill in the Gulf of Mexico. The National Institute of Environmental Health Sciences (NIEHS) is leading this research. The NIEHS is one of the National Institutes of Health (NIH) in the Department of Health and Human Services. This study will last at least 10 years. This study includes about 55,000 oil spill clean-up workers and others not directly involved in clean-up work. We will include about 24,000 of these people in the **Active Follow-up** part of the GuLF Study.

Research studies include only people who choose to take part. There will be no penalty for choosing not to join. Before agreeing to be in this research study, it is important that you read this consent form, ask any questions you have, and understand the answers to your questions. You will receive a copy of the form. Please ask the study examiner to explain any words or sections that you do not understand. When you are done and all of your questions have been answered, please sign and date the form on the last page if you agree to join the study.

What is the purpose of the study?

The purpose of this study is to learn about possible health effects of the recent oil spill in the Gulf of Mexico. We are studying clean-up workers and people who were not directly involved in clean-up jobs. Much can be learned about the effects of exposure to oil and chemicals used to clean up oil by comparing the health of those who did specific clean-up activities and those who did not. We will also study other factors that may explain why some people develop health problems and others do not. We will also study how stress and job loss can affect health, including mental health.

Who is conducting the study?

NIEHS designed and leads the study. SRA International, a professional research firm, and their subcontractors are helping NIEHS conduct the study. SRA International hired the Medical Examiners who do the home visits through a medical staffing agency called ClinForce. ClinForce hired people from the Gulf States for the study. SRA trained, equipped, and manages all field staff for NIEHS.

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.

The study research team and their roles and responsibilities are listed below:

- Dale Sandler, Ph.D. Principal Investigator, NIEHS (Overall oversight and responsibility for all parts of the study)

- Richard Kwok, Ph.D., Lead Associate Investigator, NIEHS (Oversight over the day-to-day operations of the study, exposure assessment and coordination for all parts of the study)
- Lawrence Engel, Ph.D., Associate Investigator, Memorial Sloan-Kettering and NIEHS (Oversight over study development and neurologic and laboratory test aspects of the study)
- Stephanie London, M.D., Dr.P.H., Associate Investigator, NIEHS (Oversight over the lung function aspects of the study)
- Aubrey Miller, M.D., M.P.H. Associate Investigator, NIEHS (Oversight over the medical aspects of the study)
- Christine Parks, Ph.D., Associate Investigator, NIEHS (Oversight over the immune function aspects of the study)
- Aaron Blair, Ph.D., Consultant, NCI (Consultation on overall study development and design, and consultation on assigning exposure measures in the study)
- John Hankinson, Ph.D., Consultant, Hankinson Associates (Consultation on lung function testing and interpretation, and training the home visit team)
- Mark Stenzel, Consultant, Exposure Assessment Applications, LLC. (Consultation on exposure assessment and development of study exposure measures)
- Patricia A. Stewart, Ph.D., Consultant, Stewart Exposure Assessments, LLC. (Consultation on developing the exposure assessment protocol and development of study exposure measures)

Who is paying for the study?

The National Institutes of Health (NIH) is paying for this study. The NIH is an agency of the Department of Health and Human Services in the United States Government. Some money for the study comes from a gift that was given to the National Institutes of Health by BP for oil spill health research.

Who is eligible for the study?

You are eligible for the Active Follow-up part of the study if

- You are at least 21 years old;
- You completed the GuLF Study enrollment questionnaire; and
- You did oil spill clean-up activities for at least 1 day, including paid or volunteer

work; **or**

- You were not directly involved in oil spill clean-up activities, but you worked near the oil spill or completed some oil spill worker training.

In addition, you are eligible if

- You live in one of four states (Louisiana, Alabama, Mississippi, or Florida), **or, if you do not live in one of these states,**
- You did clean-up activities as part of a Federal Civilian or Military job, regularly work in the oil industry, or were involved in activities that had the greatest chance of exposure to crude or burning oil or chemical dispersants.

What will I be asked to do?

If you agree to be in the study, we will ask you to complete all of the tasks listed below. Being in the study means you agree to do all of the tasks. But, if after trying we are not able to collect all samples or complete some tests, you will still be included in the GuLF Study.

1. Allow our staff to meet with you in your home (or some other place) for about 2.5 hours to:

Complete a health interview

The interview takes about 1 hour. We will ask you questions about oil spill clean-up activities and experiences related to the oil spill, your health and lifestyle, personal and family medical history, and places you have lived and worked.

Provide blood, hair, toenail, urine, and saliva (spit) samples

- A trained medical examiner will collect approximately 3.5 tablespoons of blood from a vein in your arm. Depending on the timing of your appointment, you may be asked not to eat or drink anything (except water) before the blood draw.
- We will ask you to give a sample of hair (from as close to your scalp as possible) and collect clippings from your toenails with a toenail clipper. If you are bald, your hair is too short, or you cannot clip your toenails, you may still be part of the study.
- We will ask you to give a first morning urine sample using the kit that was mailed to you before the visit.
- If there is a problem with the blood draw, we may ask you to provide a saliva (spit) sample.

Have a brief physical exam

A trained examiner will measure your height, weight, and blood pressure. We will measure your hips and waist over your clothes. This will take about 10 minutes. The examiner will check your urine sample for glucose (sugar) as a screening test for

possible diabetes. Some, but not all, study members will also have some clinical blood tests such as a Complete Blood Count done shortly after the home visit.

We may ask you to complete a lung function test. This test will require you to take a deep breath and exhale forcefully into a hand-held device called a spirometer. We will ask you to repeat this several times. If you use an inhaler because of a lung condition, we will ask you not to use the inhaler before this test if you are able to go without the medicine for a short time. The lung function test takes about 5 to 10 minutes. If you are not medically able to do the lung function test we will not ask you to do it. For practical reasons we will not be able to do the lung function test in states far from the gulf.

Let our staff collect dust from your home

We will use alcohol wipes to collect dust from the tops of windows and door frames in your living room, bedroom, and kitchen. In some homes we will also collect dust with a vacuum cleaner that we bring to your house. This will take 5 to 10 minutes.

2. Update contact information at least once a year.

Once a year, we will send you a form for updating your contact information and a copy of the study newsletter. We will ask you to complete and return the form, even if there are no changes. We will give you extra copies so you can let us know right away if you move or your contact information changes. This will help us send you information about the study and make sure it is possible for you to continue in the study over time. We will also give you a toll-free number you can call to let us know if you have moved or changed your phone number.

3. Complete a 30-minute telephone questionnaire every 2 years.

After the home visit, every two years we will ask you to complete a telephone questionnaire about your health. You may be able to complete the questionnaire on a secure and encrypted website. If we cannot reach you by phone, we will mail the questionnaire to you. The questionnaire will collect information about changes in your health, habits, and experiences.

4. Allow us to contact you about more detailed health studies.

We will ask some people in the study to have more detailed medical exams. The exams we will do may include more complete lung function testing, tests of neurological function (for example memory loss or performance on timed tests), and additional sample collection. ***We will give you more information about the purpose of the additional health studies at a later date. You can decide at that time if you want to take part.***

5. Allow us to follow your health through local, state, and national records.

We will use local, state, and national health information to follow changes in your health. For example, we will link identifying information about you such as your name, date of birth, address, or Social Security number to cancer registries and death certificate information. We may also use electronic medical records and Medicare and Medicaid claims information if they become available for research.

This will let us monitor health outcomes such as heart attacks, strokes, asthma or other lung diseases.

We ask you for your Social Security number. Your Social Security number is unique to you. It will help us make sure we get the correct information about changes in your health. We will store your Social Security number in a separate file that only a few people can use. The file will not be stored on computers that people can reach from the outside. The file will require a special password. We will not keep your Social Security number with other information about you. We will not share it with others except as needed to link to records about your health. If you do not want to tell us your full Social Security number, you may give just the last 4 numbers. This will help match to the correct records even though it does not uniquely identify you.

Who will interview me and collect my samples?

A trained medical examiner will interview you and collect your samples. The medical examiners were hired through a contract with a medical staffing agency called ClinForce. SRA trained the examiners and closely monitors their work for NIEHS. The examiners live in the Gulf region.

How long will the study last?

The will study last at least 10 years. The study may last more than 10 years, depending on what we learn early on. We hope that you will stay the full length of the study. However, participation is voluntary. You may quit the study at any time.

How will my study information be used?

We will use your information to learn about any health effects related to the oil spill. We will combine the results for everyone in the study for scientific papers and presentations. We will report only summary information. We will not show your individual results in any reports or presentations. The findings from the study may help with future public health responses in Gulf communities or responses to other disasters. The study will not diagnose or treat illness. If you become sick, you will need to go to your own doctor or clinic.

Will I receive any test results?

You will receive results from some laboratory tests and procedures. We will send you a report with your results and an explanation of what each result means. We will report results from tests that have been done in a certified clinical laboratory. Results from tests done in research laboratories cannot be shared.

We will let you know if we think you should share your results with a doctor or clinic. We can give you information on doctors or clinics in your area. We will also report abnormal test results to your doctor or clinic if you ask us in writing to do so. Results will not be shared with your employer or health insurance company unless you ask us to in writing.

How will my samples be used?

We will freeze your samples and store them in secure freezers. NIH owns these specimens and they will not be returned to you. At a later date, we will test your samples for research. We will look for signs of oil exposure and related health effects. We will test for evidence of other environmental exposures. We will measure a wide range of chemicals, hormones, and markers of biological changes. We will also study effects on genes and genetic factors that may interact with chemical exposures to increase or decrease the chances of getting specific conditions. The exact number and specific types of tests is not yet known. Many of the research tests will not be done on everyone in the study. We will not test for illegal drugs.

The analysis of your samples may reveal potentially useful medical information. But, it may be many years before your samples are tested. You should continue to visit your doctor or clinic for routine health care. If we discover something that could be medically useful, we will send the results to you if the tests were done in a certified lab. If we did not use a certified lab, we will re-test samples in a certified lab if we can. In some cases, results of lab tests may be hard to interpret. In other cases there may not be a certified laboratory test available. In those cases, we will send you summary results for the study and advise you to ask your doctor or clinic if anything more should be done. We will report results that are not of clear medical value in summary form only. We will share summaries of study findings with you in newsletters and other mailings.

How will my confidentiality be protected?

We will make every effort to protect your confidentiality. Laws determine what we can and cannot do. We will label your samples, questionnaires, forms, and other information with a special code number instead of your name. We will store information needed to contact you separately. We will keep everything in locked rooms or cabinets or on secure computers. Only authorized staff will see your private information.

A law called The Federal Privacy Act protects your information. People in NIH studies are not named in reports or presentations. In most cases, we will not give out information about you. But, we will send information to your doctor, insurance company, or others if you sign a release form. Note that information you share with an insurance company could affect your ability to get insurance. Sometimes we may have to give out information without your permission. For example, we may have to supply information for audits of our research. In rare cases we may have to give information to members of Congress, law enforcement officials, or other authorized people.

The study has a ***Certificate of Confidentiality*** which helps us protect the privacy and confidentiality of people in the study. The Certificate helps to prevent us from being forced to give out information that could identify you in a court of law. But, we cannot guarantee that we will never have to give out information.

A Certificate of Confidentiality does not prevent us from **voluntarily** giving out information about you. For example, we are required by law to report any abuse observed during the home visits. A Certificate of Confidentiality does not prevent you from giving out information about your involvement in this study. If you ask us in writing to send information about you to an insurer or employer, we cannot use the Certificate of Confidentiality to keep from giving out the information. This means that you must actively protect your own privacy.

Will information I provide be shared with others?

We will put information from this study into databases that others may use. Researchers may apply to use the data. We will post Information about the study and about the databases on a government website. The information that is on the public website will not identify you.

Your privacy is very important to us. We will use many safety measures to protect your identity. **However, we cannot guarantee that your identity will never become known.** We will code or “de-identify” your information. That is it will be stripped of information linking to you.

We will put coded questionnaire information, medical information and information from the tests of your coded samples in a **controlled-access** database. Researchers who want to use this information will need to get approval from an NIH Data Access Committee. The Committee will make sure that only qualified researchers use the information. Your name, street or email address, telephone number or social security number will **NOT** be put into this database. Even so, it is possible that in the future someone could figure out how to use the health or genetic information in the database to identify individuals.

Researchers who request coded study information must agree that they will use the information only for the approved research. They must agree not to identify individuals. They also must agree not to try to contact individuals in the study.

We may contact you in the future about other studies led by us or other researchers. We will do this only with the approval of the NIEHS Institutional Review Board, a committee designed to protect your rights as a research participant. Participation in these other studies is voluntary. We will explain the purpose of any additional research to you. You can decide whether or not you would like to join at that time.

We may share some samples with other researchers to answer other research questions. We will code samples that are shared. The NIEHS Institutional Review Board will also review proposals that involve new tests.

What are the benefits of participating?

You may help your community and others by helping researchers and officials learn what to expect after an oil spill. You may take pride in being part of a study that will help answer questions about the potential health effects of the Gulf oil spill. You may also

benefit from getting the results of blood and urine tests and referrals for health care. However, you will not receive medical care or other direct benefits from being in the study.

What are the risks of participating?

This study involves very minimal risk.

The questionnaires contain questions that may make you uncomfortable. You may refuse to answer any questions. You may also end the interview at any time.

There is a small risk of bruising or infection at the spot where the blood sample is drawn. Signs of infection are swelling, redness, and tenderness. The lung function test may cause coughing and a feeling of lightheadedness. These symptoms usually go away right after testing. If you have signs of infection or continue to have coughing or lightheadedness after the home visit, please contact your doctor and call the GuLF study staff at 1-855-NIH-GULF (855-644-4853).

There is some risk of breach of confidentiality. We will do everything we can to see that this does not happen. The study has a Certificate of Confidentiality to help prevent us from having to give out information that could identify you. The steps we will take to protect your confidentiality are described above.

Are there any costs for participating in this study?

There are no costs to you other than the time and effort required to complete study activities. We will pay the costs for the home visit and screening tests we do.

Will I receive compensation for my time and effort?

You will receive a \$50 dollar gift card for completing the home visit. You will receive your gift card the day of your home visit.

What if I decide not to take part?

You may decide to join this study or not. It is up to you. If you join the study you may quit at any time. Your decision will not affect any medical care or benefits you might be entitled to. If you quit the study, we will keep the information we have collected up to that point, but will not ask you for any more information. We will continue to use your information and samples. However, if we receive a written request from you asking that your samples not be used, we will cut all ties between the samples and your identifying information. This is called anonymizing the samples. We will use the anonymized samples to develop future tests or for laboratory quality control measures. You may also ask us to physically destroy the remaining samples by putting this request in writing. Information or samples already given to other researchers or placed in the de-identified database cannot be gotten back. If you decide to quit the study, please call 1-855-NIH-GULF (855-644-4853) to report your decision.

Signature of Witness

Date

Printed Name of Witness

CONSENT FOR DISCLOSURE OF INFORMATION TO DOCTORS AND CLINICS AND FOR HEALTH CARE REFERRALS

At your request, we will send test results to your doctor or clinic. We will send results for body mass index, blood pressure, urine glucose (sugar) level, lung function (if done) and, complete blood count (if done). We will only send results if one or more of the results are abnormal.

Would you like us to send abnormal laboratory results to your doctor or clinic?

Yes

Please provide contact information for your doctor or health clinic.

Name: _____

Practice Name: _____

Street address: _____

City: _____

State: _____

Zip Code: _____

Telephone Number: _____

No, I have a doctor or health clinic, but I am not interested

I do not have a doctor or health clinic.

Would you like to be referred to a local health care provider? You can be referred even if you already have a doctor

Yes

No

Signature of Participant

Date

Printed Name of Participant

Signature of Witness

Date

Printed Name of Witness

(Only for randomly selected individuals)

CONSENT FOR ADDITIONAL SAMPLE COLLECTION

You have been selected at random for an extra sample collection. This extra step is voluntary. If you agree we will collect additional tubes of blood from you and store more of your urine. We will draw four extra tubes of blood (less than 2 tablespoons) when we do the collection for the main study. You will not need to give a second urine sample. We will store an additional 40 mL from the 100 mL cup that you used to collect your urine in the morning. We will use these samples to help develop new tests and for laboratory quality control.

You may decide not to allow the extra blood collection and / or urine storage. This will not affect your participation in the main study. You may also take back your permission to use these extra samples at any time. You will have the same rights and protections as described for the main study.

There are no extra risks from giving these extra tubes of blood and urine . **You will receive an additional \$10 gift card** for letting us collect these samples (\$60 in all).

Participant Statement

I have read the consent form and received a copy for my records. My questions about the study were answered. I understand the requirements, risks, and benefits of the study. I understand that participation is voluntary and that I may quit the study at any time.

Signature of Participant

Date

Printed Name of Participant

Signature of Witness

Date

Printed Name of Witness

For those who have had the consent form read to them:

This consent document has been read and explained to me by _____
(name of reader). I volunteer to join this research study.

Signature of Participant

Date

Printed Name of Participant

Signature of Witness

Date

Printed Name of Witness