GuLF STUDY

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

OMB#0925-XXXX
EXP. XX/XXXX

INFORMED CONSENT FORM
Clinical Exam

Apply **ID label** here

Title of Study:	Gulf Long-term Follow-up Study (GuLF STUDY)
Principal Investigator:	Dale P. Sandler, PhD Epidemiology Branch National Institute of Environmental Health Sciences
Lead Associate Investigator:	Richard Kwok, PhD Epidemiology Branch National Institute of Environmental Health Sciences
Associate Investigators	Lawrence Engel, PhD Department of Epidemiology Gillings School of Global Public Health University of North Carolina at Chapel Hill and Epidemiology Branch National Institute of Environmental Health Sciences Stephanie London, MD, DrPH Epidemiology Branch National Institute of Environmental Health Sciences Aubrey Miller, MD, MPH Office of the Director National Institute of Environmental Health Sciences Christine Parks, PhD Epidemiology Branch National Institute of Environmental Health Sciences David A. Welsh, MD School of Medicine Louisiana State University Errol D. Crook, MD College of Medicine University of Southern Alabama
Consultants	Aaron Blair, PhD Scientist Emeritus National Cancer Institute David Abramson, MD Columbia University Robert L. Jensen, PhD University of Utah Fredric Gerr, MD University of Iowa Diane Rohlman,PhD University of Iowa

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You are being asked to participate in a clinical exam for the GuLF STUDY, a research study on possible health effects of the 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. About 6,000 participants will be invited to take part in this exam.

Research studies include only people who choose to take part. There will be no penalty for choosing not to take part in the exam. Before agreeing to do this part of the 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 research staff 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 exam is learn more about possible health effects of the oil spill in the Gulf of Mexico. We are studying clean-up workers as well as people who were not directly involved in clean-up jobs. Much can be learned about the effects of exposure to oil and to 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.

Who is conducting the study?

NIEHS designed and leads the study. SRA International (SRA), a professional research firm, and their subcontractors are helping NIEHS conduct the exams. SRA partners with university medical centers to carry out the clinical exam. The clinical examinations will be carried out by collaborators at the University of South Alabama and Louisiana State University Health Sciences Center. SRA 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.

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

- **Dale Sandler, PhD,** Principal Investigator, NIEHS (Overall oversight and responsibility for all parts of the study)
- **Richard Kwok, PhD,** 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, PhD,** Associate Investigator, University of North Carolina at Chapel Hill and NIEHS (Oversight of study development and neurologic and laboratory test aspects of the study)
- **Stephanie London, MD, DrPH,** Associate Investigator, NIEHS (Oversight over the lung function aspects of the study)
- **Aubrey Miller, MD, MPH,** Associate Investigator, NIEHS (Oversight over the medical aspects of the study)
- **Christine Parks, PhD,** Associate Investigator, NIEHS (Oversight over the immune function aspects of the study)

- **Aaron Blair, PhD,** Consultant, NCI (Consultation on overall study development and design, and consultation on measuring exposures to oil and oil dispersants)
- **Robert L. Jensen, PhD,** University of Utah (Consultation on pulmonary function testing and interpretation)
- **David A. Welsh, MD,** Associate Investigator, Louisiana State University (Louisiana Clinical Site Director)
- **Errol D. Crook, MD,** Associate Investigator, University of Southern Alabama (Alabama Clinical Site Director)
- **David Abramson, PhD** Consultant, Columbia University (Consultation on mental health assessment)
- **Fredric Gerr, MD,** Consultant, University of Iowa (Oversight over the neurobehavioral and neurological areas of the study)
- **Diane Rohlman, PhD,** Consultant, University of Iowa (Oversight over the neurobehavioral and neurological areas of the study)

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 clinical exam?

You are eligible for the clinical exam, if…

- You are currently enrolled in the GuLF STUDY
- You completed a home exam

What will I be asked to do?

If you agree to the exam, you will be asked to visit a clinical exam site for about 4 hours. During the exam, you will be asked to -

1. Provide blood, hair, toenail, saliva and urine samples
   - We will collect about 3.5 tablespoons (54.5mL) of blood from a vein in your arm.
   - We will collect a small sample of your hair and collect small clippings from your toenails.
   - We will ask you to give a urine sample.
   - We may ask you to collect several saliva samples at home and mail them back to the clinic.
2. Have your vital signs and body measurements taken
   - We will measure your heart rate and blood pressure.
   - We will measure your height and weight.
   - We will measure your hips and waist over your clothes.

3. Complete lung function tests, including -.

Spirometry

- You will be asked to take a deep breath and exhale forcefully into a device called a spirometer that measures your lung function. You will be asked to do this several times.
- Next, we will ask you to take an inhaler medicine to open your airways. After 15 minutes, we will ask you to repeat the lung function test.
- 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.

Other lung tests

- You will be asked to breathe into a small machine that measures exhaled nitric oxide, a possible sign of lung inflammation.
- You may be asked to breathe into a plastic tube to collect moisture from the air you breathe out. The moisture that is collected will be tested for other signs of lung inflammation.

4. Complete tests of nervous system function

- You will be asked to complete tests that measure balance, vision, and how well your nerves work.
- You will be asked to complete a series of tests to measure your attention, memory, reaction time, and coordination.

5. Complete a questionnaire about your health

- You will be asked questions about your physical and mental health, as well as questions about factors that may influence your exam results.

Who will conduct my clinical exam?

The exam will be conducted by trained research staff members who are affiliated with university medical centers. SRA, the study coordinating center, and their consultants and advisors have trained the research staff and closely monitor their work for NIEHS.

How will my study information be used?

We will use your information to learn about any health effects related to the oil spill and your experiences during and after the event. 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, treat or cure any 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 at the end of the visit. We will report results from tests that are clinically relevant. Results from tests done in research laboratories will not be shared because their meaning for your health will not be clear.

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. Results will not be shared with your employer, health insurance company, or health care provider 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 privacy be protected?

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, laws determine what we can and cannot do. A law called **The Federal Privacy Act** protects your information. 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. But, we cannot guarantee that we will never have to give out information. In rare cases, NIH has been required to give the information collected during a research study to members of Congress, law enforcement officials, or other authorized people. However, even in those cases, we try to protect your identity.

For added protection, the study also 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. Even with the Certificate of Confidentiality, however, we may voluntarily report some things we observe during the clinical exam, such as indications that someone may be planning to hurt themselves or others.

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 a doctor, 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 qualified researchers may use. Researchers may apply to use the data. We will post information about the study and the databases, but not the databases themselves, on a government website. Because your privacy is very important to us, the information that is on the public website will not identify you.

We will use many safety measures to protect your identity. However, we cannot guarantee that your identity will never become known. We will put the answers you give us to the questionnaires, medical information and information from the tests of your coded samples in a ***controlled-access*** database. As stated above, we will code or "de-identify" your information. That is, it will be stripped of information linking to you. 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 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 screening 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 some questions that may make you uncomfortable. You may refuse to answer any questions. You may also end the clinical visit 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 tests may cause coughing, rapid heart rate, and a feeling of lightheadedness. These symptoms usually go away right after testing. If you have signs of infection or continue to have coughing, rapid heart rate, or lightheadedness after the clinical exam visit, please contact your doctor and call the clinic that you visited.

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.

While it is very unlikely that any study procedures will cause more than mild, temporary discomfort, clinical sites will arrange for short-term medical care for health problems that arise during the visit. However, the clinic will not pay for the costs of this care. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the federal government, the National Institutes of Health, SRA, or clinical exam sites. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

Are there any costs for participating in this study?

There are no costs to you other than the time and effort required to complete the exam. We will pay the costs for the clinical visit and tests we do.

Will I receive compensation for my time and effort?

You will receive a gift card for $100 for completing the clinical exam and will be reimbursed for your travel based on your distance from the clinic. You will receive your gift card when you complete your exam. Participants who are selected to provide saliva samples will receive an additional $20 gift card. There is no cost associated with accepting the gift card(s).

What if I decide not to take part?

You may decide to complete the exam or not. It is completely up to you. If you participate in the exam, 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.

The study researchers may decide to withdraw you from the study with or without your consent. This might happen if you are found not to be eligible for the study. If you are not able to complete the study requirements or you have missed too many steps, the investigators may send you a letter to tell you that you will be dropped from the study.

Who should I contact for more information about the study?

The clinical staff will answer questions during the exam. You may also call the study toll-free at 1-855-NIH-GULF (1-855-644-4853) at any time if you have questions. Ask to speak to a member of the GuLF STUDY staff or the principal investigator, Dr. Dale Sandler.

If you have questions about your rights as a research participant you may call the NIEHS Institutional Review Board at 1-919-541-3852.

PARTICIPANT'S CONSENT TO VOLUNTEER FOR THIS STUDY

Enter the participant's study ID here:

___ ___ ___ ___ ___ ___ ___

To give us your consent to volunteer to participate in this study, please indicate in either the left or right columns below whether you required assistance from an adult other than the GuLF STUDY clinical examiner in reading or reviewing this informed consent form.

No witness required

I was able to review this form with clinical staff and did not require any other assistance.

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

My signature

My printed name

Clinical staff signature

Clinical staff printed name

Date of visit

Witness required

The third-party adult signing as the Witness below and a clinical staff member have assisted the participant in reading and reviewing this informed consent form.

- The participant has received a copy of this form for his/her records.
- The participant's questions about the study were answered.
- The participant understands the requirements, risks, and benefits of the study.
- The participant understands that their participation is voluntary and that they may quit the study at any time.

Witness signature

Witness' printed name

Participant's signature (or mark)

Participant's printed name

Clinical Examiner's signature

Clinical Examiner's printed name

Date of visit