Appendix D: Informed Consent Form

OMB #: 0925-xxxx
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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. A large group of clean-up workers and other people who were not directly involved in clean-up work will be in this study. In all, about 55,000 people will be included. About 24,000 of these will be included 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 participate. Before agreeing to take part 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 participate in 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 who were not directly involved in clean-up activities. 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. All of these partners follow guidelines and procedures approved by the NIH Office of Human Subjects Research. This office exists to protect people who participate in research studies.

Who is funding the study?

The study is funded by the National Institutes of Health (NIH). The NIH is an agency of the Department of Health and Human Services in the United States

Government. Some of the funding 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 participated in 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 likelihood 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, you will be asked to complete the tasks listed below.

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 before the blood draw.
- You will be asked to provide a few strands of hair (as close to your scalp as possible) and collect clippings from your toenails with a toenail clipper.

If you are bald or cannot clip your toenails, you may still be part of the study.

- You will be asked to provide a first morning urine sample. A urine collection kit will be mailed to you before the visit.
- If there is a problem with the blood draw, you may be asked to provide a saliva (spit) sample.

Have a brief physical exam

A trained examiner will measure your height, weight, and blood pressure. Your hip and waist circumference will be measured 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 participants will also have some clinical blood tests such as a Complete Blood Count done shortly after the home visit.

You may be asked 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. You will be asked 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 qualified to do the lung function test you will not be asked to do it. For practical reasons we will not be able to offer the lung function test in communities far from the gulf. Allow our staff to collect dust from your home

Our staff will use a vacuum to collect dust from your living room, bedroom, and kitchen. 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 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 participants to have more detailed medical studies. The exams may include more complete lung function testing, tests of neurological function (e.g. memory loss or performance on timed tests), and additional sample collection. ***You will be given 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 names and other identifying information to cancer registries and death certificate information. We may also use electronic medical records and Medicare and Medicaid claims data if they become available for research. This will let us monitor health outcomes such as heart attacks, strokes, asthma or other respiratory 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 secure file and will not share it with others. If you do not want to tell us your full Social Security number, you may give just the last 4 digits. This will help match to the correct records even though it does not uniquely identify you.

How long will my participation 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 participate for the full length of the study. However, participation is voluntary. You may withdraw from the study at any time.

How will my study information be used?

Your information will be used to learn about any health effects related to the oil spill. The results for everyone in the study will be combined for scientific papers and presentations. Only summaries will be given. Your individual results will not be shown 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?

Your samples will be frozen and stored in secure freezers. 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. Results that are not of clear medical value will be reported in summary form only. We will share summaries of study findings with you in newsletters and other mailings.

How will my confidentiality be protected?

Every effort will be made to protect your confidentiality. Laws determine what we can and cannot do. Your samples, questionnaires, forms, and data will be labeled with a special code number instead of your name. Information needed to contact you will be stored separately. Everything will be kept 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 data. 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 data for audits of our research. In rare cases we may have to give data to members of Congress, law enforcement officials, or other authorized people.

The study has been given a ***Certificate of Confidentiality*** under a federal law [Section 301(d) of the Public Health Service Act]. The Certificate helps us protect the privacy of people in the study. The Certificate prevents us from being forced to give out identifying information in court.. 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?

Data from this study will be put into databases that others may use. Researchers may apply to use the data. Information about the study and about the databases will be posted 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***. Your data will be coded or "de-identified". That is it will be stripped of information linking to you.

Coded questionnaire data, medical information and information from the analyses of your coded samples will be put in a ***controlled-access*** database. Researchers who want to use this data will need to get approval from an NIH Data Access Committee. The Committee will make sure that only qualified researchers use the data. 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 data must agree that they will use the data 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. The purpose of any additional research will be explained to you. You can decide whether or not you would like to participate at that time.

We may share some samples with other researchers to answer other research questions. Samples that are shared will be coded. 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. Costs for the home visit and screening tests will be paid by the study.

Will I receive compensation for my time and effort?

You will receive a $45 dollar gift card for completing the home visit. You will receive your gift card by mail within 2 to 3 weeks of completing the home visit. .

What if I decide not to participate?

You may decide to participate in this study or not. It is up to you. If you join the study you may withdraw at any time. Your decision will not affect any medical care or benefits you might be entitled to. If you withdraw from 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 data 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. The anonymized samples will be useful to develop future assays or for laboratory quality control measures. You may also ask us to physically destroy the remaining samples by putting this request in writing. Data or samples that have already been given to other researchers or placed in the de-identified database cannot be withdrawn. If you decide to withdraw from the study, please call 1-855-NIH-GULF (855-644-4853) to report your decision.

The investigators conducting the study may decide to withdraw you from the study without your consent. This might happen if it 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 examiner will answer questions during the home visit. You may 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 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 withdraw from 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 participate in this research.

Signature of Participant | Date

Printed Name of Participant

Signature of Witness | Date

Printed Name of Witness

CONSENT FOR DISCLOSURE OF INFORMATION TO HEALTLH CARE PROVIDERS AND FOR HEALTH CARE REFERRALS

At your request, we will send test results to your health care provider. 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 health care provider?

___ Yes

Please provide contact information for your health care provider.

Name: _____
Practice Name: _____
Street address: _____
_____
City: _____
State: _____
Zip Code: _____
Telephone Number: _____

___ No, I have a health care provider, but I am not interested

___ I do not have a health care provider.

Are you interested in receiving referral to a local health care provider? You are eligible for a referral even if you have a regular health care provider.

___ 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. We will draw four extra tubes (less than 2 tablespoons) when we do the collection for the main study. We will also keep more of your urine sample than we would ordinarily keep. These samples will be used to help develop new assays and for laboratory quality control.

You may decide not to allow the extra blood collection. This will not affect your participation in the main study. You may also withdraw 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. **You will receive an additional $10 gift certificate** for allowing us to collect these samples ($55 in all). You will receive your gift cards by mail within 2 to 3 weeks of the home visit.

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 withdraw from 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 participate in this research.

Signature of Participant	Date
Printed Name of Participant	
Signature of Witness	Date
Printed Name of Witness	