Attachment 6: Informed Consent Form

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)
CENTERS FOR DISEASE CONTROL
U.S. PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a NIOSH research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

I. DESCRIPTION

1. Title: Personal Flotation Devices (PFDs) and Commercial Fishermen: Preconceptions and Evaluations in Actual Use

2. Project Officer: Jennifer Lincoln, PhD

3. Purpose and Benefits:
   - The purpose of this study is to evaluate a variety of modern PFDs with commercial fishermen to discover the features and qualities that they like and dislike.
   - There are no benefits to the individual respondent.
   - Findings from the PFD evaluations will help PFD manufacturers design PFDs that better meet the needs of the fishing industry.
   - The PFD evaluations will also supply information to fishermen about which types of PFDs worked best.
   - This study has the potential to greatly benefit the fishing industry. It will provide information to fishermen that may encourage them to wear PFDs while they work.

II. CONDITIONS OF THE STUDY

1. You will be assigned a PFD and asked to wear it whenever you are out on deck, for the duration of one month. You will be asked to complete a short form to evaluate your PFD after one day and then one month.

2. Some discomfort associated with wearing the PFD may occur as part of your evaluation of the PFD. If discomfort becomes excessive you should document the problems and discontinue wearing the PFD. Wearing a PFD may increase your risk of entanglement. If you have any comments about the tests/procedures, you should contact Jennifer Lincoln, 907-271-2383.

3. This PFD evaluation is unique. There are no alternative test procedures to collect these data.

4. If you have questions about this research, contact Dr. Jennifer Lincoln, 907-271-2383. If you have questions about your rights as a member of this study, contact Cheryl F. Estill, Chair NIOSH Human Subjects Review Board, 513-533-8591

5. Your participation is voluntary. You may withdraw your consent and your participation in this study at any time. There is no penalty or loss of benefits for withdrawing. Upon completion of the study, you are invited to keep the PFD that you evaluated or another PFD of your choice from the study.

6. NIOSH will provide you with the results from this study by mail once the data collection and analysis is complete.

7. Injury or harm from this project is unlikely. But if it results, medical care is not provided, other than

emergency treatment. If you are injured through negligence of a NIOSH employee you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your contact point is: Public Health Service Claims Office: (301) 443-1904. If you are injured or harmed through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government. If an injury or harm should occur to you as the result of your participation, you also should contact: Cheryl F. Estill, Chair NIOSH HSRB, 513-533-8591.

III. USE OF INFORMATION

This study is being done by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control (CDC), a government agency in the Department of Health and Human Services. We collect this information in order to learn about various kinds of work hazards that may influence the health of the American worker.

NIOSH is allowed to collect and keep information about you, including your results from this study, along with your social security number (if applicable), because of three laws passed by Congress. These laws are:

1. The Public Health Service Act (42 U.S.C 241)
2. The Occupational Safety and Health Act (29 U.S.C. 669)
3. The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

You will decide whether you want to provide us with this information by being in this study. You are free to choose not to be in this study. It is up to you. If the information we are collecting is maintained and retrieved by personal identifiers, such as your name and social security number, it will become part of the CDC record system and we will protect it to the extent allowed by law. You should know, however, that there are conditions under the Privacy Act when we could be authorized to release this information to outside sources. These conditions under which we might release this information are listed in Appendix A (the Privacy Act).

IV. SIGNATURES

I have read this consent form and received a copy of the conditions for data release under the Privacy Act (Appendix A). I agree to participate in this study.

PARTICIPANT_____Age _____
(signature)

I, the NIOSH representative, have accurately described this study to the participant.

REPRESENTATIVE_____Date_____
(signature)

Appendix A

The Information you provide will become part of the CDC Privacy Act System, 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records" and may be disclosed to the following.

- **Appropriate state or local heath departments to report communicable diseases.**
- **A State Cancer Registry to report cases of cancer where the state has a legal reporting program providing for confidentiality.**
- **Private contractors assisting NIOSH.**
- **Collaborating researchers under certain circumstances to conduct further investigations.**
- **One or more potential sources of vital statistics to make determinations of death, health status or to find last known address.**
- **The Department of Justice or the Department of Labor in the event of litigation.**
- **Congressional offices assisting an individual in locating his or her records.**

You may request an accounting of the disclosures made by NIOSH.

Except for these and other permissible disclosures authorized by the Privacy Act, or in limited circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.