Attachment 9: Additional Information for HSRB Review

Potential Risks to Respondents

There are no potential risks to respondents during phase 1 (the initial questionnaire). Fishermen will be asked to complete a short survey that asks only non-intrusive questions about their perceptions and opinions. There are no sensitive questions, and no identifying questions. No names or other identifying information will be collected.

Phase 2 involves fisherman wearing and evaluating a PFD over the course of one month. During the evaluation period the fishermen will need to be contacted two times; therefore, name and contact information will need to be collected. This presents the potential risk of being identified as a study participant. Additionally, wearing the PFD may present the potential risk of catching a part of the PFD on lines or other gear.

Protection against Risks

There are no risks to participants in phase 1. In phase 2, the risk of being identified will be reduced by the researchers following a strict procedure to ensure confidentiality. For those participants who continue into phase 2, a unique ID number will be affixed to the back of each survey at the time of administration, and the participant's name, phone number, and address will be recorded. Two datasets will be created, one containing the ID and personal identifying information, the other containing the ID and responses to the survey items. After the data collection and analyses are completed and the results are sent to the participants (as dictated by the Informed Consent Form), no further contact with the participants will be necessary and the dataset with the personal identifying information will be permanently deleted.

The datasets will be stored in a secure, password protected location on the NIOSH network. A password protected backup copy of the dataset without identifiers will be stored off-site in a secure location. The hard copies of the surveys will be maintained in a locked file cabinet. Access to this information will be restricted to NIOSH scientists directly involved with the study. At the end of the data collection the dataset with the personal identifiers will be permanently deleted. Respondents are advised of this in the "Instructions to Respondents" (Appendix Attachment 5: Instructions to Respondents) and in the consent form (Appendix Attachment 6: Informed Consent Form) which also includes information on the authority and purpose for data collection, that participation is voluntary, that responses will not be used in enforcement actions against them, and that the survey results will be made available to industry, safety organizations, federal agencies, and other interested parties in a summary format only -- without any personal identifiers. Data will be treated as confidential, unless otherwise compelled by law.

To protect against the risk of the PFD becoming entangled in gear, researchers will select PFDs that have the least potential for entanglement. In fact, even if a fisherman were pulled overboard due to such an entanglement, the PFD would then provide the flotation necessary for rescue.

Risks/Benefits Ratio

As explained in section A1 of the Supporting Statement, from 1990 to 2005, 71 commercial fishermen drowned subsequent to a fall overboard in Alaska. None of the victims were wearing a PFD, and sadly, many were within minutes of being rescued when they lost their strength and sank. Those deaths could have clearly been prevented if the victims had been wearing PFDs.

The potential risk described above (entanglement leading to a fall overboard) seems far outweighed by the reduction in risk associated with their wearing PFDs.

The expected benefits of the study to the broader community of fishermen include the increased use of PFDs. If this occurs, it can be expected to greatly reduce of the risk of drowning due to falls overboard, a highly preventable event.

Informed Consent Procedures

The phase 1 questionnaire is anonymous and has no potential risk to respondents. A waiver of informed consent has been requested for respondents who only complete the phase 1 initial questionnaire based on the following four criteria from CFR 46.116(d):

1. The research involves no more than minimal risk to the subjects. As stated in Attachment 9: Additional Information for HSRB Review, there are no potential risks to respondents during phase 1 (the initial questionnaire). Fishermen will be asked to complete a short survey that asks only non-intrusive questions about their perceptions and opinions. There are no sensitive questions, and no identifying questions. No names or other identifying information will be collected.

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects. No names or other identifying information will be collected, so responses to the survey items will be anonymous.

3. The research could not practicably be carried out without the waiver or alteration. The sample size for phase 1 is large and we expect that few fishermen on the docks would be willing to take the time to complete the questionnaire if a formal consent process was included.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Since no identifiers are being collected on this anonymous questionnaire, no contact is possible or necessary after participation.

For those fishermen participating in the phase 2 PFD evaluations, a signed informed consent form will be required (Appendix Attachment 6). The consent form being used is the standard NIOSH consent form adapted to this specific project.

Commercial fishing boat captains (skippers) have absolute power of what happens on-board. The skippers will all be informed of the study, and asked to participate in the evaluations, like

the crewmembers. The most ideal situation will be those vessels where the skipper and all crewmembers agree to participate. However, we cannot compel a skipper to allow the study on his vessel, and by the same token the skipper cannot be permitted to use his absolute power to compel his crew to participate. The informed consent form will be a prerequisite for participation.

Emergency Procedures

If an emergency develops during a study participant's involvement in the research that is related to wearing a PFD, the situation will be evaluated immediately to determine if there is a similar risk to other participants. Possible actions to alleviate the risk include removing a particular PFD from the study if it is found to present a unique hazard; or the termination of the study if it is found that the emergency situation presents a risk to all of the participants.

If circumstances arise in which a participant's continued participation seems to pose a risk to his or her health or safety, he will be removed from the study. In addition, the informed consent document (a copy of which will be given to each participant) states that a participant is free to withdraw from the study at any time.

Participants and research assistants will be instructed to contact the investigators at AFS if there are any concerns about participants' safety, or any possible health risks are seen that might make the study unsafe for any participants. Concerns will be evaluated and acted upon immediately using the emergency procedures detailed above.

Changes to the Protocol

<u>Part B, Section 2 (starting on page 13) now reads:</u>

Data collection will take place in three locations in Southwest Alaska: Dutch Harbor, Dillingham, and Naknek. Eight trained research assistants will assist in administering the phase 1 surveys and phase 2 evaluations. The research assistants will all complete ethics training and a workshop on how to administer the questionnaires. All assistants will be working off of the same script for recruiting participants and asking the questions. The specific activities that the research assistants will perform are described below.

The method for selecting the sample and administering the study will be as follows:

1. In each of the three communities in Southwest Alaska (Dutch Harbor, Dillingham and Naknek) researchers will complete phase 1 and initiate phase 2 one week prior the start of each fishery. The three towns are communities where commercial fishing is a major industry, so it is expected that shortly before the start of a fishery there will be many fishermen out preparing their vessels and gear.
2. Researchers will walk down each of the piers at the harbors and contact every fisherman on the pier and administer the questionnaire until the required quota for that fishery is that town is reached. Refusals to participate will be recorded in order to calculate the response rate.

3. When a fisherman is contacted that is willing to participate, the researcher will explain the study and the questionnaire and then administer the questionnaire to the fisherman, asking the questions and recording the responses.
4. When a questionnaire is completed, the researcher will describe the phase 2 portion of the study to the fisherman and ask for participation in testing a PFD. If the fisherman agrees to continue in the study by evaluating a PFD, the researcher will assign and deliver a PFD to the fisherman and further explain the procedures for doing the test.
5. The researcher will then proceed along the pier repeating the process for all fishermen present.
6. As data collection proceeds, numbers of fishermen in each fishery participating in each phase will be monitored. Once the required sample size for phase 2 (the PFD evaluations) has been reached, researchers will no longer ask fishermen completing the phase 1 survey to participate in the phase 2 evaluations. Once the sample size for phase 1 has been reached, data collection activities will cease.
7. For those fishermen participating in phase 2, two PFD evaluation forms will be administered by the local research assistants. The first form will be given to the fishermen with the PFD and we will ask that it be filled out after one or two days of wearing the PFD. On the vessel's first return trip to port to offload fish, the research assistants will collect the completed forms or have the form completed at that time if it was not filled out at sea. Using this method all of the first evaluations should be done within the first week. The date that the form was filled out will be recorded on the form. A unique ID will be affixed to the forms to keep the forms linked in the dataset.
8. After one month of wearing the PFD, the research assistants will make contact and have the second and final evaluation form filled out.

The research assistants will have extra PFDs available to replace any that become lost or damaged. They will also have all the spare parts available to recharge any PFDs that were inflated.

Part B, Section 1, 3rd paragraph (page 12) now reads:

Regarding vulnerable populations, we will allow pregnant women to participate in the study if they are encountered during the sample selection process. They can judge for themselves whether their pregnancy is a hindrance to wearing a PFD, and can give or withhold informed consent. Other vulnerable populations such as prisoners and children under 18 are not expected to be found in the sampling universe (at-work commercial fishermen in Southwest Alaska), but in the event that a member of one those vulnerable populations is discovered during the sampling process (perhaps a child under 18 on a family run fishing vessel), he/she will not be asked to participate. Their inclusion would introduce complications regarding the ability to give informed consent free of coercion, and/or the need for parental consent. Dealing with these issues would strain or exceed our logistical resources; therefore we will exclude such persons from the study.