DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date April 16, 2008

From Chair, NIOSH HSRB

Subject Report of NIOSH HSRB -- Protocol No. HSRB 08-DSR-01XP "Personal Flotation Devices (PFDs) and Commercial Fishermen: Preconceptions and Evaluations in Actual Use" Approval of Protocol

To Jennifer Lincoln, Ph.D.
Project Officer, OD, DSR
Through: /Director, OD, DSR ____ ____

General Comments and IRB Actions

I received your response (E-mail dated 2/28/08) regarding the subject protocol and find it is responsive to the issues raised in my February 20, 2008, HSRB Report 2. Unfortunately, your E-mail response was sent to the NIOSH HSRB Office global mailbox during HHS mail migration set up, and was therefore not recognized as being received until 4/14/08 when co-PI, Devin Lucas, contacted the NIOSH HSRB to request status and the oversight was identified. Additionally, it is required that protocol submissions/resubmissions be approved by the submitting branch/division OD offices prior to their being received by the NIOSH HSRB; and that generally, hard copy submissions follow (are sent in addition to) electronic submissions.

However, your 2/28/08 E-mail response regarding the subject protocol was reviewed using the expedited procedure in that it presents no more than minimal risk and involves research employing survey, interview, oral history, focus group, program evaluation, (criterion #7) as provided for in 45CFR46.110. Effective 4/16/08, the revised protocol and consent document are **approved** for one year and will serve as the documents of record for this study (renewal date 1/23/2009). However if you make any substantive changes, or any adverse reactions occur in any study participants, please notify me immediately.

Additionally, please contact Kathy Masterson, Administrator for the NIOSH HSRB to set up the proper collaborator (3) agreements for: 1) U.S. Coast Guard; 2) MSEA-The Alaska Marine Safety Education Association; and 3) NPFOV-The North Pacific Fishing Vessel Owners Association; and any additional collaborators engaged in this research.

Protocol Issues – None.
Consent Form Issues – None.
Addenda Issues (Scripts, questionnaires, brochures, etc.) - None

End of report

Kathy Masterson
for Cherie Fairfield Estill, M.S., P.E.

cc:
HSRB 08-DSR-01XP

New Protocol

0.1379 Centers for Disease Control and Prevention
NIOSH HSRB

Date received
1/11/08
resent 2/14/08

Signature Page for Human Research Review
Protocols and Related Documentation

Use this signature page when submitting HRPO forms to your center-level Human Subjects Contact. When submitting materials with these forms, please consecutively number all pages, beginning with the protocol title page and followed by consent form(s) and ancillary documents. See *HRPO Guide: Overview* for further details. **NOTE: IRB (Institutional Review Board) refers to the NIOSH HSRB (National Institute for Occupational Safety and Health (NIOSH) Human Subjects Review Board (HSRB) of the CDC Human Research Protection Office (HRPO).**

1 Protocol identifiers

CAN# _____ (optional)

Leave protocol ID blank if not yet assigned.

CDC protocol ID: HSRB 08-DSR-01XP Protocol version number _____ version date _____

Protocol title: Personal Flotation Devices and Commercial Fishermen: Preconceptions and Evaluations in Actual Use

Amendment number (if applicable): _____

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Jennifer Lincoln, PhD	jxw7	8443	NIOSH/OD/AFS
Principal investigator (required)	Jennifer Lincoln, PhD	jxw7	8443	NIOSH/OD/AFS

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/division is the national center or equivalent and division or equivalent, or coordinating center or office if submitted at that level.

3 Forms submitted with this signature page

Check all that apply in the appropriate column.

IRB-reviewed protocols

- ☒ 0.1250: Initial Review by IRB
- ☐ 0.1251: Continuing Review of Approved Protocol
- ☐ 0.1252: Review of Changes to Approved Protocol
- ☐ 0.1254: Incident Report
- ☐ 0.1254S: Supplemental Adverse Event Report
- ☐ 0.1253: End of Human Research Review
- ☒ 0.1370: CDC's Research Partners
- ☐ 0.1371: CDC Rely on a Non-CDC IRB
- ☐ 0.1372: Outside Institution Rely on a CDC IRB
- ☐ 0.1373: CDC Cover an Individual Investigator

Exempted protocols

- ☐ 0.1250X: Initial Review for Exemption
- ☐ 0.1251X: Continuing Review of Exempted Protocol
- ☐ 0.1252X: Review of Changes to Exempted Protocol
- ☐ 0.1253: End of Human Research Review
- ☐ 0.1370: CDC's Research Partners

K. Master 1/14/08 revised

4 Signatures

As principal investigator, I hereby accept responsibility for conducting this CDC-sponsored research project in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date	Remarks
Principal CDC Investigator:	1-4-08	

As a supervisor of the principal investigator, I hereby accept responsibility for ensuring that this CDC-sponsored research project is conducted in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date	Remarks
Team Lead:	1-4-08	Check if PI is Team Lead: ☑
Branch Official (e.g., Chief or Senior Scientist):	1-10-08	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS):	1/11/08	Check if PI is Division Official: ☐

I concur that this CDC-sponsored research project is consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants* and with other applicable CDC and national center policies.

Signature	Date	Remarks
Chair, NIOSH HSRB: for Kathy Masterson for Gail McGowan	4/16/08	APPROVED Expedited Review; Minimal Risk, as provided for in 45CFR46.110(7).
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		

5 Additional comments

6 Reminder regarding other regulatory clearance processes

The principal investigator is responsible for obtaining other regulatory reviews as needed, which may include OMB clearance under the Paperwork Reduction Act (PRA) for federally sponsored information collections. Approval by or exemption from the IRB is unrelated to OMB clearance requirements under the PRA. For more information on whether your study requires clearance under PRA or other regulations, please consult the appropriate officials within your national center.

Request for Initial Review by an Institutional Review Board

Use this form to submit a protocol for its first review by a CDC IRB or a non-CDC IRB. If seeking review by a non-CDC IRB, also include form 0.1371. See *HRPO Guide: IRB Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

Leave protocol ID blank if not yet assigned.

CDC protocol ID: HSRB 08-DSR-01XP Protocol version number version date

Protocol title: Personal Flotation Devices and Commercial Fishermen: Preconceptions and Evaluations in Actual Use

Suggested keywords (optional). Enter each term in a separate cell:

Commercial Fishing	Occupational Stafety	Alaska
Personal Flotation Device		

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Jennifer Lincoln, PhD	jxw7	8443	NIOSH/OD/AFS
Principal investigator (required)	Jennifer Lincoln, PhD	jxw7	8443	NIOSH/OD/AFS
Investigator 2	Philip Somervell, PhD	gjx7	18423	NIOSH/OD/AFS
Investigator 3	Devin Lucas, MS	fok1	11190	NIOSH/OD/AFS
Investigator 4				
Investigator 5				

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/division is the national center (or equivalent) and division (or equivalent), or coordinating center or office if submitted at that level.

List all other CDC investigators, if any (name and degrees, user ID, SEV #, CDC NC/division):

3 CDC's role in project

Check yes or no for each of the following.

☒y ☐n CDC employees or agents will obtain data by intervening or interacting with participants.

☒y ☐n CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens.

☐y ☒n CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens.

☒y ☐n CDC employees will provide substantial technical assistance or oversight.

☒y ☐n CDC employees will participate as co-authors in presentation(s) or publication(s).

"Agents" includes on-site contractors, fellows, and others appointed or retained to work at a CDC facility conducting activities under the auspices of CDC.

4 CDC's research partners

Research partners include *all* direct and indirect recipients of CDC funding (e.g., grants, cooperative agreements, contracts, subcontracts, purchase orders) and other CDC support (e.g., identifiable private information, supplies, products, drugs, or other tangible support) for this research activity, as well as collaborators who do not receive such support. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☒ No research partners.

☒ Research partners are listed on form 0.1370, which accompanies this form.

5 Study participants—planned demographic frequencies

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites. See *HRPO Guide: IRB Review Cycle* for definitions.

Number of participants	400
Location of participants	
Participating at domestic sites	400
Participating at foreign sites	0
Sex/Gender of participants	
Female	0
Male	0
Sex/gender not available	400
Ethnicity of participants	
Hispanic or Latino	0
Not Hispanic or Latino	0
Ethnicity not available	400
Race of participants	
American Indian or Alaska Native	0
Asian	0
Black or African American	0
Native Hawaiian or Other Pacific Islander	0
White	0
More than one race	0
Race not available	400

Comments on demographics

6 Regulation and policy

6.1 Mode of IRB review on CDC's behalf

Location of IRB (check one):

☒ CDC IRB

☐ Non-CDC IRB through IRB authorization agreement [submit form 0.1371]

Institution or organization providing IRB review:

IRB registration number (if known):

Federalwide assurance number (if any):

Suggested level of risk to subjects (check one):

☒ Minimal

☐ Greater than minimal

Suggested level of IRB review (check one):

See *HRPO Worksheet for Expedited Review* for detailed assistance. If relying on a non-CDC IRB, please indicate the level of review that you think is appropriate under human research regulations.

☐ Convened-board review is suggested

- ☐ Not eligible for expedited review. For example, poses greater than minimal risk; involves use of drug, biologic, or device under IND or IDE; involves collection of large amount of blood; use of x-rays or microwaves; anesthesia; or physically invasive procedures
- ☐ Other specified reason:

☒ Expedited review is suggested, under the following categories (check all that apply):

- ☐ 1a Study of drugs not requiring Investigational New Drug exemption from FDA
- ☐ 1b Study of medical devices not requiring Investigational Device Exemption from FDA
- ☐ 2a Collection of blood from healthy, nonpregnant adults; below volume limit, minimally invasive
- ☐ 2b Collection of blood from other adults and children; below volume limit, minimally invasive
- ☐ 3 Prospective noninvasive collection of biological specimens for research purposes
- ☐ 4 Collection of data through routine, noninvasive procedures, involving no general anesthesia, sedation, x-rays, or microwaves
- ☐ 5 Research that uses previously collected materials
- ☐ 6 Collection of data from voice, video, digital, or image recordings made for research purposes
- ☒ 7 Research that uses interview, program evaluation, human factors, or quality assurance methods

6.2 Vulnerable populations

Characterize the intention to include each of the following vulnerable populations. Choose one option in each row, and indicate the page(s) where inclusion or exclusion is justified in the protocol.

	Targeted	Allowed	Excluded	NA	Page(s)
Pregnant women or fetuses	☐	☒	☐	☐	12
Children (including viable neonates)	☐	☐	☒	☐	12
Prisoners	☐	☐	☒	☐	12

Describe other groups of potentially vulnerable subjects intended to be included or excluded, such as neonates of uncertain viability or nonviable neonates, persons with mental disabilities, or persons with economic or educational disadvantages.

6.3 Free and informed consent

Characterize requested changes to required features of the informed consent process. If a waiver is requested, enter the page number of the protocol where the waiver is justified.

K. Master 3/20/18 for Phase 1.

Which exceptions to the consent process are requested? Check all that apply:

☒ Waiver or alteration of elements of informed consent for adults pg

☐ Waiver of assent for children capable of providing assent pg

☐ Waiver of parental permission pg

Which exceptions to documentation of informed consent are requested? Check all that apply:

- ☐ Waiver of documentation of informed consent for adults pg
- ☐ Waiver of documentation of assent for children capable of providing assent pg
- ☐ Waiver of documentation of parental permission pg
- ☐ Waiver or alteration of authorization under HIPAA Privacy Rule pg

How is it shown that the consent process is in understandable language? Check all that apply:

- ☒ Reading level has been estimated pg 8
- ☐ Comprehension tool is provided pg
- ☐ Short form is provided pg
- ☐ Translation planned or performed
  - ☐ Certified translation/translator pg
  - ☐ Translation and back-translation to/from target language(s) pg
  - ☐ Other method (specify:) pg

6.4 Other regulation and policy considerations

Check all that apply.

If requesting the exception to the PHS policy on informing those tested about HIV serostatus, enter the page number of the protocol where the waiver is justified.

- ☐ Exception is request to PHS informing those tested about HIV serostatus. pg
- ☐ Human genetic testing is planned now or in the future.
- ☐ This study includes a registrable clinical trial.
- ☐ This study involves long-term storage of identifiable biological specimens.
- ☐ This study involves a drug, biologic, or device.

  See HRPO Worksheet to Determine FDA Regulatory Coverage for guidance on whether or not FDA regulations apply.
- ☐ This study will be conducted under an Investigational New Drug (IND) exemption or Investigational Device Exemption (IDE).

  IND/IDE number(s):

6.5 Confidentiality protections

If at least one research site is within the US, then check either Granted, Pending, or No in each row. If no sites are within the US, then check NA in each row.

	Granted	Pending	No	NA
Certificate of Confidentiality (301(d))	☐	☐	☒	☐
Assurance of Confidentiality (308(d))	☐	☐	☒	☐

Describe any other formal confidentiality protections that are planned or are in place:

7 Material submitted with this form

Check all that apply. Describe additional material in the comments section.

☒ Complete protocol

☒ Peer reviewers' comments or division waiver (NIOSH)

☒ Consent, assent, and permission documents or scripts

☐ Other information for recruits or participants (e.g., ads, brochures, flyers, scripts)

☒ Data collection instruments (e.g., questionnaires, interview scripts, record abstraction tools)

☐ Certification of IRB approval or exemption for research partners

8 Additional comments

The NIOSH standard consent form is being used, but has been modified to fit our project and to reduce the reading level (standard consent form tested at the 12th grade level and was revised down to the 10th grade level.

Research Assistants who aide in data collection will complete ethics training prior to doing any field work. We will submit a form 1370 when we have identified the people who will be working as research assistants.

CDC's Research Partners

Use this form to report current information on CDC's research partners whenever a partner institution or individual is added or information changes. Supply individual name and SEV number only for investigators collaborating with CDC under an individual investigator agreement (IIA). See *HRPO Guide: CDC's Research Partners* and either the *HRPO Worksheet for Basic Tracking of Research Partners* or the *HRPO Worksheet for Advanced Tracking of Research Partners* for details on how to complete this form.

Leave protocol ID blank if not yet assigned.

CDC protocol ID: HSRB 08-DSR-01XP Protocol version number version date

Protocol title: Personal Flotation Devices (PFDs) and Commercial Fishermen: Preconceptions and Evaluations in Actual Use

Partner 1

Institution name: US Coast Guard
Institution location: Dutch Harbor, Alaska
Individual name (IIA only): Charlie Medlicott & Chris Woodley
Reporting status: Initial report
Regulatory coverage: Engaged/non-exempt
Financial support: No financial support
Support award number:
Support end date:
Nonfinancial support: Nonfinancial support?
FWA number:
SEV number (IIA only):
IRB review status: IRB review status?
IRB approval expiration date:
Comments: Engaged Agreement to be set up prior to engagement

Partner 2

Institution name: Alaska Marine Safety Education Association
Institution location: Sitka Alaska
Individual name (IIA only): Jerry Dzugan
Reporting status: Initial report
Regulatory coverage: Engaged? Exempt?
Financial support: Contract/subcontract
Support award number:
Support end date:
Nonfinancial support: Nonfinancial support?
FWA number:
SEV number (IIA only):
IRB review status: IRB review status?
IRB approval expiration date:
Comments: Engaged - Agreement to be set up prior to engagement

Partner 3

Institution name: North Pacific Fishing Vessel Owners Association
Institution location: Seattle WA
Individual name (IIA only): Leslie Hughes
Reporting status: Initial report
Regulatory coverage: Engaged/non-exempt
Financial support: Contract/subcontract
Support award number:
Support end date:
Nonfinancial support: Nonfinancial support?
FWA number:
SEV number (IIA only):
IRB review status: IRB review status?
IRB approval expiration date:
Comments: Engaged Agreement to be set up prior to engagement.

Partner 4

Institution name:
Institution location:
Individual name (IIA only):
Reporting status: Reporting status?
Regulatory coverage: Engaged? Exempt?
Financial support: Financial support?
Support award number:
Support end date:
Nonfinancial support: Nonfinancial support?
FWA number:
SEV number (IIA only):
IRB review status: IRB review status?
IRB approval expiration date:
Comments: