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: _____ 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.

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.