DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date June 11, 2020

From Kathleen MacMahon, DVM, MS
Reviewer, NIOSH Institutional Review Board

Subject IRB Approval of New NIOSH Protocol 19-NIOSH-51, "Understanding Long-term Respiratory Morbidity in Former Styrene-Exposed Workers" (Expedited)

To Suzanne Tomasi, DVM, MPH, DACVPM
Project Officer, NIOSH/RHD

The NIOSH IRB reviewed the request for approval of new protocol 19-NIOSH-51, "Understanding Long-term Respiratory Morbidity in Former Styrene-Exposed Workers." The IRB determined the study poses minimal risk to subjects. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories (2a), (4), (5) and (7). Continuing review is not required for this protocol since it is eligible for expedited review.

Due to the funding and collection of identifiable, sensitive information the project is determined to be covered by a Certificate of Confidentiality under section 301(d) of the Public Health Service Act.

If other institutions involved in this protocol are being awarded NIOSH funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

Investigators are required to report incidents to the HRPP in accordance with CDC/NIOSH policy and procedure. Any proposed changes to the protocol should be submitted as an amendment to the protocol for NIOSH IRB approval before they are implemented.

If you have any questions, please contact the NIOSH Human Research Protection Program (513) 533-8591 or e-mail: NIOSH IRB Mailbox.

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. See *HRPO Guide: Non-Exempt 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: 19-NIOSH-51 Protocol version number 3.1 version date 04/06/2020

Protocol title: Understanding Long-term Respiratory Morbidity in Former Styrene-Exposed Workers

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

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	CITI Course Expiration Date	CDC CIO/division
Primary contact (required)	Suzanne Tomasi, DVM, MPH	yxc4	10/17/2021	NIOSH/RHD
Principal investigator (required)	Suzanne Tomasi, DVM, MPH	yxc4	10/17/2021	NIOSH/RHD
Co-Investigator	Randall J. Nett, MD, MPH	gge5	10/29/2021	NIOSH/RHD
Co-Investigator	Jean Cox-Ganser, PhD	jjc8	12/18/2021	NIOSH/RHD
Co-Investigator	Stephen Bertke, PhD	inh4	06/05/2021	NIOSH/DSHEFS
Co-Investigator	Alice Shumate, PhD, MPH	wii5	12/31/2021	NIOSH/WSD

CITI Course Expiration Date is the latest expiration date for the CITI Biomedical Research and RCR Combined or Social & Behavioral Research and RCR Combined course required by CDC (expires every 3 years). An expiration date must be entered for each investigator. If required training is expired or found expired before IRB review, the protocol will not be reviewed or placed on administrative hold (e.g. cease processing for approval) by HRPO until requirements are met. List all other CDC investigators, if any (name and degrees, user ID, CITI Course Expiration Date, CDC CIO/Division):

List all other CDC investigators or staff engaged in the conduct of the research, if any (name and degrees, user ID, CITI Course Expiration Date, CDC CIO/division):

Nirmala Thapa, MPH, nui7, CITI expiration data 12/13/2021

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.

NOTE: If both options above are checked "NO" this does not meet the requirement for reliance on a Non-CDC IRB

☐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 Study Subjects

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites.

Total Count of subjects: 676

Comments on demographics: Boatbuilder cohort, 85% male, 94% white, older worker population

5 Regulation and policy

5.1 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): _____

Federal-wide assurance number (if any): _____

Suggested level of risk to subjects (check one):

☒ Minimal

☐ Greater than minimal

Suggested level of IRB review (check one):

☐ 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, non-pregnant 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

5.2 Additional Considerations

Indicate the extent to which the following populations will be included in the research. 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	☐	☐	☒	☐	18
Prisoners	☐	☐	☒	☐	18
Children (including viable neonates)	☐	☐	☒	☐	18

Describe other groups of potentially vulnerable subjects intended to be included or excluded, such as individuals with impaired decision making capacity and economically or educationally disadvantaged individuals. N/A

5.3 Free and informed consent

§46.116(a)(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. (Reasonable Person Standard)

Please explain here how the study meets this standard and ensure the explanation is in the protocol:

Our research population, recruitment, and consent process is described in detail in the human subject section of the protocol starting on page 20. NIOSH has been following this cohort since 1978. We plan to introduce them to the research project through an information session held in Bellingham, WA and Kelso, WA. Cohort members who agree to participate in the research project will be consented by a trained NIOSH investigator who will explain the purpose of the study, the study procedures, risks to participate in the study, and answer questions. Each participant will be required to give his or her written informed consent.

§46.116(a)(5) Except for broad consent obtained in accordance with paragraph (d) *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens*. §46.116(a)(5)(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (Key Information Standard)

Please describe here how the study meets this standard:

This study meets the requirements of 45 CFR 46.116(a)(5)(i), the Key Information standard, in that a concise and focused presentation of the key information is presented to prospective research participants at the beginning of the informed consent process in clearly-understandable language. The Flesch-Kincaid Grade Level of the consent document has been graded at 9.3.

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 22
- ☐ 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 _____

5.4 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): _____

5.5 Confidentiality protections

CDC supported research commenced or ongoing after December 13, 2016 and in which identifiable, sensitive information is collected, as defined by Section 301(d) of the Public Health Service (PHS) Act, is deemed issued a Certificate of Confidentiality and therefore required to protect the privacy of individuals who are subjects of such research. Indicate one of the following:

- ☐ Not applicable
- ☒ Certificate of Confidentiality maybe applicable to study; pg 23 of the protocol where the protections are described.

Additional Comments:

Results will be incorporated into a single database where each subject will be identified by a unique study number. For all data, confidentiality will be assured by using only the unique study number in all analyses

5.6 Clinical Trial

Is this a clinical trial? ☐ Yes ☒ No

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. §46.102(b)

Please answer the following questions. If the answers to the 4 questions are yes, the study meets the definition of a clinical trial.

☒ y ☐ n Does the study involve human participants?
☐ y ☒ n Are the participants prospectively assigned to an intervention?
☐ y ☒ n Is the study designed to evaluate the effect of the intervention on the participants?
☐ y ☒ n Is the effect being evaluated a health-related biomedical or behavioral outcome?

Studies intended solely to refine measures are not considered clinical trials.
Studies that involve secondary research with biological specimens or health information are not clinical trials.

6 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

7 Additional comments

Please accept the attached protocol titled "Understanding Long-term Respiratory Morbidity in Former Styrene-Exposed Workers". Through the NORA process, this protocol has undergone peer review and all reviewer comments have been addressed.

8 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

☐ Additional partners are listed on ancillary 1370 form

Partner 1 Duke University Institution name: _____ Institution location: Durham, NC Individual name (IIA only): Scott Palmer, MD Reporting status: Initial Report Regulatory coverage Not Engaged Financial support Contract/Sub-Contract Support award number: _____ Support end date: _____ Nonfinancial support: No Financial Support FWA number: _____ SEV number (IIA only): _____ IRB review status: Not Applicable IRB approval expiration date: _____ Comments: Not engaged in human subjects research. DCMorris	**Partner 2** Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status [Enter Status Here] Regulatory coverage Not Engaged Financial support [Enter Status Here] Support award number: _____ Support end date: _____ Nonfinancial support [Enter Status Here] FWA number: _____ SEV number (IIA only): _____ IRB review status [Enter Status Here] IRB approval expiration date: _____ Comments: _____
Partner 3 Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status [Enter Status Here] Regulatory coverage: [Enter Status Here] Financial support: [Enter Status Here] Support award number: _____ Support end date: _____ Nonfinancial support: [Enter Status Here] FWA number: _____ SEV number (IIA only): _____ IRB review status [Enter Status Here] IRB approval expiration date: _____ Comments: _____	**Partner 4** Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status [Enter Status Here] Regulatory coverage: [Enter Status Here] Financial support: [Enter Status Here] Support award number: _____ Support end date: _____ Nonfinancial support: [Enter Status Here] FWA number: _____ SEV number (IIA only): _____ IRB review status [Enter Status Here] IRB approval expiration date: _____ Comments: _____
Partner 5 Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: [Enter Status Here] Regulatory coverage: [Enter Status Here] Financial support: [Enter Status Here] Support award number: _____ Support end date: _____ Nonfinancial support: [Enter Status Here] FWA number: _____ SEV number (IIA only): _____ IRB review status [Enter Status Here] IRB approval expiration date: _____ Comments: _____	**Partner 6** Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status [Enter Status Here] Regulatory coverage: [Enter Status Here] Financial support: [Enter Status Here] Support award number: _____ Support end date: _____ Nonfinancial support: [Enter Status Here] FWA number: _____ SEV number (IIA only): _____ IRB review status [Enter Status Here] IRB approval expiration date: _____ Comments: _____

9 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: Suzanne E. Tomasi -S Digitally signed by Suzanne E. Tomasi -S Date: 2020.04.08 08:02:35 -04'00'	04/08/2020	

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:		Check if PI is Team Lead: ☐
Branch Official (e.g., Chief or Senior Scientist): Randall J. Nett -S6 Digitally signed by Randall J. Nett -S6 Date: 2020.06.09 11:36:45 -04'00'		Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): Jean M. Cox-ganser -S Digitally signed by Jean M. Cox-ganser -S Date: 2020.06.09 11:58:24 -04'00'		Check if PI is Division Official: ☐