DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date October 25, 2012

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH IRB (HSRB) – Protocol No. HSRB 12-DRDS-06XP "Research to Inform the Prevention of Asthma in Health Care" Approval of Protocol with Stipulations – Requires Amendment Prior to Engagement

To Paul Henneberger, Sc.D.
Michael Humann, Ph.D.
Project Officers, FSB, DRDS
Through: /Chief, FSB, DRDS ____ ____
/Director, FSB, DRDS ____ ____

General Comments and IRB Actions

I received your revised protocol and consent script (memo dated 10/10/2012) for the subject protocol and find that it is responsive to the issues raised in my 9/19/2012 NIOSH IRB (HSRB) courtesy report. Your protocol was reviewed using the expedited procedure in that it presents no more than minimal risk and involves collection of data through noninvasive procedures routinely involved in clinical practice (criterion #4); and research employing a human factors evaluation (criterion #7); as provided for in 45CFR46.110. Your request for a waiver of documentation of informed consent is approved per 45CFR46.117 (c) (2) in "(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context."

Per our telecom today (10/25/2012) where you informed me that NIOSH IRB (HSRB) approval of your protocol is required for OMB submission. You also informed me that you were seeking NIOSH IRB approval of the content of your questionnaire, the telephone recruitment script including consent, and written communications prior to translating these materials into Spanish. Additionally, you informed me that you need NIOSH IRB approval to move forward on the project with your Union partner (SEIU). Normally the NIOSH IRB requires a complete and final version of the protocol (protocol of record) prior to granting approval. However, you have made the case that NIOSH IRB approval of procedures and content of materials is essential prior to finalizing the tools for implementing the protocol. I have reviewed your NIOSH IRB review responses and revised protocol and determined that your responses and revisions are adequate with exceptions noted below. **I approve the protocol with the following stipulations:** Before contacting or interacting in anyway with participants you will provide the NIOSH IRB with (1) a final on screen version of the questionnaire (no draft watermarks); (2) Spanish translation with back translation or confirmation of questionnaire translation; recruitment and consent scripts; post card; and letters; (3) approved/signed confidentiality agreement from SEIU-CC; (4) FWA for SEIU-CC and an approved/signed SEIU Agreement CDC 0.1372A to defer IRB review to a CDC IRB (NIOSH IRB) in place; and (5) any deviations from the present protocol of record will require submission of a formal Request for Changes to an IRB Approved Protocol by submitting via hard copy CDC forms 0.1379 (signature page), 0.1252 (amendment request), 0.1370 (non CDC collaborator, if have), a clean copy of the revised protocol and a highlighted copy (track changes or pen/ink) of the revised protocol (all changes highlighted). Electronic submission of your amendment request may facilitate review, but it is not required. The current revised protocol and consent document (dated 10/25/2012) will serve as the documents of record for this study (renewal date 10/25/2013). However, if you make any substantive changes to the protocol or if any adverse reactions occur in any study participants, please notify me immediately (phone: 513-533-8591 or E-mail MToraason@cdc.gov).

The procedure for requesting annual continuing review is to send 45-60 days prior to renewal date completed hard copy forms CDC 0.1379 (signature page), 0.1251 (continuing review request), 0.1370 (non CDC collaborator, if have), a copy of your current consent form (if still consenting or recruiting). An electronic submission of your continuing review may facilitate review, but it is not required.

Please note that the Service Employees International Union (SEIU) does currently possess an active FWA00018478 registered with the HHS Office for Human Research Protections. The current SEIU FWA signatory provided by OHRP is Myra Glassman, 209 West Jackson Boulevard, 2nd Floor, Chicago, IL 60606, ph: 312-980-9007 and E-mail myra.glassman@seiuhcil.org. Generally, HHS OHRP allows for a limited (or only one) FWA registration per institution (SEIU). You may consider contacting Ms. Glassman regarding your research activity to see whether it would be appropriate for SEIU FWA00018478 to be utilized for your research or not. Please follow-up with Kathy Masterson to ensure the proper assurances and agreements are in place, prior to engagement. Thank you.

Protocol Issues, Consent Form Issues, Addenda Issues – None.

End of Report

Kathy Masterson
for Mark A. Toraason, Ph.D.

cc:
HSRB 12-DRDS-06XP

NEW PROTOCOL

0.1379 Centers for Disease Control and Prevention Date received

NIOSH HSRB

8/28/12 hc
8/21/12 elec

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 12-DRDS-06XP Protocol version number 1 version date 08/14/2012

Protocol title: Research to Inform the Prevention of Athma in Healthcare

Amendment number (if applicable): .....

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Michael Humann, PhD	UZO1	2150	NIOSH/DRDS
Principal investigator (required)	Paul Henneberger, ScD	PKH0	3291	NIOSH/DRDS
	~~M. Abbas Virji, ScD~~ Co PI?	FNB8	16946	NIOSH/DRDS

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

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: Paul K. Hammelberger	8/14/12	
Supervisor: [illegible]	8/14/2012	

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:	8/20/12	Check if PI is Team Lead: ☐
Branch Official (e.g., Chief or Senior Scientist):	8/20/12	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS):	08/21/12	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 Mark Tolocman **Date** 10-25-12 **Remarks** Minimal Risk Requir approval to obtain OMB Approval Translation to Spanish after OMB approval

Chair, NIOSH HSRB:

Expedited Review; Minimal Risk; as provided for in 45CFR 46.110 (b)(1) category(s) 4 + 7;
Approved for one year; renewal date ~~10/25/2013~~.

Other Clearance Official:
(e.g., ~~Confidentiality Officer~~, Coordinating Center/Office Official)

Approval 10/25/12 with Stipulations

5 Additional comments

Before interaction, IRB needs final screen Version of questionnaire and Spanish translation of all Documents; SEIU Confidentiality Agreement & 1372A Agreement in place.

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.

APPROVED

8/28/12 hc
8/21/12 elec

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 12-DRDS-06XP Protocol version number 1 version date 08/14/2012

Protocol title: Research to Inform the Prevention of Asthma in Healthcare

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

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Michael Humann, PhD	UZO1	2159	NIOSH/DRDS
Principal investigator (required)	Paul Henneberger, ScD	PKH0	3291	NIOSH/DRDS
Investigator 2	~~M. Abbas Virji, ScD~~	PNB8	16946	NIOSH/DRDS
Investigator 3	Jean Cox-Ganser, PhD	JJC8	2692	NIOSH/DRDS
Investigator 4	M. Abbas Virji, ScD	PNBP	16946	" "
Investigator 5				

One PI per KM 8/6/12 email

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).

MT 10-24-12 PI response

"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	~~5,000~~ 12,000
Location of participants	
Participating at domestic sites	~~5,000~~ 12,000
Participating at foreign sites	0
Sex/Gender of participants	
Female	~~3,500~~ 8,400
Male	~~1,500~~ 3,600
Sex/gender not available	0
Ethnicity of participants	
Hispanic or Latino	~~500~~ 1200
Not Hispanic or Latino	~~2600~~ 6240
Ethnicity not available	~~1,900~~ 4560
Race of participants	
American Indian or Alaska Native	~~5~~ 12
Asian	~~350~~ 840
Black or African American	~~2,000~~ 4800
Native Hawaiian or Other Pacific Islander	0
White	~~300~~ 720
More than one race	0
Race not available	~~2,345~~ 5628

MT 12-9-2014 per PI change

Comments on demographics

Demographic information for overall membership population provided by SEIU 1199

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

10-24-12 MT

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	☐	☒	☐	☒	
Children (including viable neonates)	☐	☐	☐	☒	
Prisoners	☐	☐	☐	☒	

MT 10-24-12

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 13

☐ 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 13
☐ 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 13
☐ Comprehension tool is provided pg
☒ Short form is provided pg
☒ Translation planned or performed
  ☒ Certified translation/translator pg 11
  ☐ 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:

The Service Employees International Union (SEIU) Communications Center, who will be conducted the telephone interviews and distributing the recruitment materal, has an internal system for protecting confidentiality. However, prior to recruitment and data collection they will obtain a Federal Wide Assurance (FWA) for the protection of human subjects.

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

Date received
8/28/12 hc
8/21/12 elec

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 12-DRDS-06XP Protocol version number 1 version date 08/14/2012

Protocol title: Research to Inform the Prevention of Asthma in Healthcare

Partner 1

Institution name: Service Employees International Union (SEIU) Communications Center
Institution location: 330 West 42nd Street, 7th Floor, New York, NY 10035
Individual name (IIA only):
Reporting status: Initial report
Regulatory coverage: Engaged/non-exempt
Financial support: Contract/subcontract
Support award number: Has not been assigned yet
Support end date: TBD
Nonfinancial support: No nonfinancial support
FWA number: ~~TBD~~ FWA 00018478 ?
SEV number (IIA only):
IRB review status: Relying on CDC IRB
IRB approval expiration date:
Comments: Support award number will be determined once contract has gone through the CDC system. FWA will be obtained prior to interactions with participants.

Need Signed 1372A in place prior to engagement. kn

Partner 2

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:

Partner 3

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:

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:

Partner 5

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:

Partner 6

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:

Partner 7

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:

Partner 8

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:

Partner 9

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:

Partner 10

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: