DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date December 4, 2020

From Kathy Masterson
IRB Administrator, NIOSH Institutional Review Board

Subject IRB Approval of Continuation of NIOSH Protocol 13-HELD-03XP, "Factors Influencing the Transmission of Influenza" (Expedited)

To William G. Lindsley, PhD
Project Officer, HELD, NIOSH

The NIOSH IRB has reviewed and approved your request to continue protocol 13-HELD-03XP for the maximum allowable period of one year and it will expire on November 17, 2021. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories (3), (4) and (7).

The IRB determined the study poses no more than minimal risk to subjects.

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 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.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB along with available IRB approvals from all collaborators. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. **To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request along with all completed supporting documentation at least six weeks before the protocol's expiration date of November 17, 2021.**

Any problems of a serious nature must be brought to the immediate attention of the NIOSH IRB, and 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 CDC Human Research Protection Program (513) 533-8591 or e-mail: cin-hsrb@cdc.gov.

Request for Subsequent Action of IRB-Approved Protocol

Use this form to submit a protocol for continuing review or amendment by a CDC IRB or a non-CDC IRB. [See 45 CFR 46.109(e).] See *HRPO Guide: Non-Exempt Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

CDC protocol ID: 13-HELD-03XP Protocol version number 5 Version date 10/05/2018

Protocol title: Factors Influencing the Transmission of Influenza

☒ Continuing Review
☐ Review of changes

☐ *Requesting transition to the 2018 Common Rule *(*Optional)*

Note: This may require changes to the study, including informed consent documents, to comply with the 2018 Common Rule

2 Key CDC personnel

☐ **No change** in key CDC personnel. If no changes, please list only the primary contact and principal investigator.

	Name and degrees (FirstName LastName, Degrees)	User ID	CITI Course Expiration Date	CDC CIO/division
Primary contact (required)	William G. Lindsley, PhD	wdl7	04/01/2022	NIOSH/HELD
Principal investigator (required)	William G. Lindsley, PhD	wdl7	04/01/2022	NIOSH/HELD
Co-Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				

Notice: *Re-Verify if required CITI training is expired or found expired for any personnel listed on this protocol. Lapse in current training can result in removal from the study or suspension of the study until requirements are met.*

List all other CDC investigators. Include name and degrees, user ID, CITI Course Expiration Date, CDC CIO/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 subjects.
☐y ☒n CDC employees or agents will obtain or use identifiable (including coded) private data or biospecimens.
☒y ☐n CDC employees or agents will obtain or use anonymous or unlinked data or biospecimens.
☒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

Have any subjects been enrolled in the last 12 months? ☐ yes ☒ no

Total number of subjects needed for study: 240 Total number of subjects enrolled to date: 118

Comments on sample size:

Additional subjects total will allow us to recruit about another 60 subjects with influenza and 60 healthy subjects

4.1 Contact status

"Contact" means intervention or interaction with subjects, such as recruitment, screening, obtaining consent, enrollment, and collection of data and biospecimens directly from subjects. Check one of the following.

☐ Study is not designed to involve research-related contact with subjects (e.g., research using existing records); study activities involve only access to or analysis of data or biospecimens and writing reports.

☒ Study is designed to involve contact with participants. Check one of the following:

- ☐ Contact with subjects has not yet begun.
- ☒ Contact with subjects has begun and continues; this may include follow-up for debriefing or notification of results.
- ☐ Contact with subjects is completed; study activities involve only data analysis or report writing.

4.2 Consent status

"Consent" includes adult consent, child assent, and parental permission. Check one of the following.

☐ The IRB previously waived all requirements both to obtain and to document consent in this study.

☐ Although not waived, there is no further need to obtain or document consent (e.g., enrollment is complete).

☒ *Subjects will be asked to provide consent (with or without documentation).

** If you check the third box, please include all current consent, assent, and parental permission materials (e.g., scripts, documents) from each study site with this submission.*

5 Study status—overall conduct *(This section can be skipped for amendments)*

[Comment 5.1] Summary of research activities to date. Briefly summarize study progress and interim findings. Include the number of potential subjects who declined enrollment and the number who withdrew from the study. If this study involves a registrable clinical trial, summarize registration status.

In our most recent studies, we collected the aerosol particles produced when each patient breathed normally into a mask for 20 minutes. About a third of potential subjects declined to enroll in the study. No participants withdrew after enrollment. We intend to continue these studies with a similar apparatus, but we will measure the samples by mass spectroscopy and PCR rather than by culturing the virus.

[Comment 5.2] Summary of study changes reviewed and approved since the last continuation. Do not include changes submitted with or before approval of this continuation but not yet approved.

None

[Comment 5.3] Summary of any recent literature or other information relevant to the research study (not limited to information with CDC co-authorship).

Our work and work by other groups has shown that patients with influenza expel potentially infectious virus in airborne particles as they cough and breathe. Our focus is now shifting to analyzing the content of the airborne particles and understanding how this relates to the production of potentially infectious aerosols and the body's response to the influenza infection.

[Comment 5.4] Summary of all adverse events to date. In particular, address adverse events that were serious, unexpected (or more frequent or severe than expected), or at least possibly related to the research.

No adverse events have occurred.

[Comment 5.5] Summary of (a) incidents that are not adverse events and (b) other substantial concerns since last continuation.

No incidents or substantial concerns have arisen.

[Comment 5.6] List and include copies of progress or monitoring reports on safety or compliance (e.g., site monitor, safety review, DSM report, multi-center trial report, but not reports to PGO).

N/A

[Comment 5.7] Summary of remaining research activities, emphasizing future contact with subjects, use of identifiable private data and biospecimens, and preparation of primary reports.

Subjects will be enrolled in the study and tested using our new aerosol collection system. Additional studies will be prepared when we have significant results.

6 Regulation and policy

6.1 Vulnerable populations

Check one of the following:

☐ **Change** in vulnerable populations (added or dropped).

☒ **No Change**

6.2 Free and informed consent

Check one of the following:

☐ **Change** in consent process, forms, or approved waivers.

☒ **No Change**

6.3 Other regulation and policy considerations

Check one of the following:

☐ **Change** in other regulation and policy considerations.

- Exception to PHS policy regarding notification of HIV test results
- Human genetic testing
- Inclusion of a registrable clinical trial or change in registration status
- Plans for long-term storage of identifiable biospecimens
- Involvement of drug, biologic, or device, including Investigational New Drug or Investigational Device Exemption status (See *HRPO Worksheet to Determine FDA Regulatory Coverage* for guidance on whether or not FDA regulations apply.)

☒ **No Change**

6.4 Confidentiality protections

Check one of the following:

☐ **Change** in confidentiality protections (e.g., granted, applied for, denied).

☒ **No Change**

7 Summary of proposed changes

Describe and justify proposed modifications to the protocol. Include page numbers in reference to clean version and tracked version. Continue summary below in additional comments or in supplemental document if necessary.

8 Suggested 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 if this is a new request]

Institution or organization providing IRB review: ___

IRB registration number: _____

Federal-wide assurance number: _____

Suggested level of risk to subjects (check one):

☐ Proposed changes to protocol are minor

☒ Minimal

☐ Greater than minimal

Suggested level of IRB review (check one):

☐ Convened-board review is suggested

Reason for convened review: _____

☒ 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 materials collected solely for non-research purposes
- ☐ 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

Continuing review of research previously approved by the convened IRB where

- ☐ 8a The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects
- ☐ 8b No subjects have been enrolled and no additional risks have been identified
- ☐ 8c The remaining research activities are limited to data analysis
- ☐ 9 Continuing review of research, not under IND/IDE, where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

9 CDC's research partners

Research partners include *all* direct and indirect recipients of CDC funding (e.g., grants, cooperative agreements, contracts, subcontracts, purchase orders) other CDC support (e.g., identifiable private information, supplies, products, drugs, or other tangible support and collaborators who do not receive such support. Include current information on partners added or dropped since the last review using form 0.1370. Check one of the following.

☒ No research partners have been added since the last review.

☐ Research partners have been added and are listed on form 0.1370, which accompanies this form.

☐ One or more research partners no longer collaborate for this study, and are listed as follows**:**

10 Material submitted with this form

Check all that apply. Describe additional material in the comments section. Required items are indicated. Optional items may be requested by HRPO or the IRB.

Clean	Tracked	
☒	☐	Complete protocol
☒	☐	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 supported/nonexempt partner
☐		Progress and monitoring reports (recommended when available)

11 Additional comments

☐ Additional partners are listed on ancillary 1370 form

Partner 1 West Virginia University
Institution name: _____
Institution location: Morgantown, WV 26508
Individual name (IIA only): _____
Reporting status: Previously Reported
Regulatory coverage: Engaged/Non-Exempt
Financial support: No Financial Support
Support award number: _____
Support end date: _____
Nonfinancial support: No Financial Support
FWA number: 00005078
HS Training (IIA only): Other Human Subject Training-Yes
IRB review status: Relying on CDC IRB
IRB approval expiration date: 11/17/2020
Comments: Agreement 1372A in place KM

Partner 2
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: _____
HS Training (IIA only): [Enter Status Here]
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: _____
HS Training (IIA only): [Enter Status Here]
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: _____
HS Training (IIA only): [Enter Status Here]
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: _____
HS Training (IIA only): [Enter Status Here]
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: _____
HS Training (IIA only): [Enter Status Here]
IRB review status: [Enter Status Here]
IRB approval expiration date: _____
Comments: _____

12 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: William G. Lindsley -S Digitally signed by William G. Lindsley -S Date: 2020.11.16 14:21:50 -05'00'	_____	_____

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: John D. Noti -S Digitally signed by John D. Noti -S Date: 2020.11.16 14:08:00 -05'00'	_____	Check if PI is Team Lead: ☐ _____
Branch Official (e.g., Chief or Senior Scientist): John D. Noti -S Digitally signed by John D. Noti -S Date: 2020.11.16 14:08:25 -05'00'	_____	Check if PI is Branch Official: ☐ _____
Division Official (e.g., Director or ADS): Paul D. Siegel -S Digitally signed by Paul D. Siegel -S Date: 2020.11.16 14:48:11 -05'00'	11/16/2020	Check if PI is Division Official: ☐ _____