DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date November 17, 2017

From Kathy Masterson, CIP
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 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, 2018. 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 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, 2018.**

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.

Signature Page for Human Research Review

Protocols and Related Documentation

Anniversary Date: 11/17/2018

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.

1 Protocol Identifiers

CAN#: 939ZUMK (optional)

Leave protocol ID blank if not yet assigned.

CDC Protocol ID: 13-HELD-03XP Protocol Version Number: 4 Version Date: 10/05/2017

Protocol Title:

Factors Influencing the Transmission of Influenza

Amendment Number (if applicable): 2

2 Key CDC Personnel

	Name and Degrees (First Name Last Name, Degrees)	User ID	CDC SEV #	CDC NC/Division
Primary Contact Phone Number (required)	William G. Lindsley, PhD (304) 285-6336	wdl7	7980	NIOSH/HELD
Principal Investigator Phone Number (required)	William G. Lindsley, PhD (304) 285-6336	wdl7	7980	NIOSH/HELD

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 Signed	Remarks
Principal CDC Investigator: William G. Lindsley -S Digitally signed by William G. Lindsley -S Date: 2017.10.06 08:26:32 -04'00'	10/06/2017	

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 Signed	Remarks
Team Lead: John D. Noti -S Digitally signed by John D. Noti -S Date: 2017.10.06 08:55:19 -04'00'	10/06/2017	☐ PI is Team Lead
Branch Official (e.g., Chief or Senior Scientist): John D. Noti -S Digitally signed by John D. Noti -S Date: 2017.10.06 08:51:32 -04'00'	10/06/2017	☐ PI is Branch Official
Division Official (e.g., Director or ADS): Paul D. Siegel -S9 Digitally signed by Paul D. Siegel -S9 Date: 2017.10.06 14:21:25 -04'00'	10/06/2017	☐ 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 Signed	Remarks
/Chair NIOSH IRB: Kathy J. Masterson -S Digitally signed by Kathy J. Masterson -S Date: 2017.11.17 14:11:52 -05'00'	11/17/2017	conduct continues Approved for IRB Co-Chair, Gail McConnell, VMD, MPH
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.