Building Related Asthma Research in Public Schools (New)

Principal Investigator:

Jean M. Cox-Ganser, PhD
NIOSH
Division of Respiratory Disease Studies
Phone: 304-285-5818
Fax: 304-285-5820

Reviewed January, 2008

Appendix D: HSRB Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date April 18, 2008

From Chair, NIOSH HSRB

Subject Report of NIOSH HSRB -- Protocol No. HSRB 08-DRDS-01 "Leveraging Implications of Building-Related Asthma Research in Public Schools" Approval of Protocol

To Jean Cox-Ganser, Ph.D.
Project Officer, FSB, DRDS
Through: /Chief, FSB, DRDS ____ ____
/Director, DRDS ____ ____

General Comments and IRB Actions

I received your response (memo dated April 14, 2008) and find that it is responsive to the issues raised in my April 8, 2008, convened review/report 2 granting deferred approval; as well as convened review/report 1 of March 11, 2008. The revised protocol and consent document are **approved** for one year and will serve as the documents of record for this study (dated 4/18/08). As stated in HSRB review/report 2 dated 4/8/08, this protocol can be reviewed/renewed in the future on an expedited basis. The next review date for this protocol is 3/11/2009. However, if you make any substantive changes to the protocol, or if any adverse reactions occur in any study participants, please notify me immediately.

Also, prior to your sending notification letters to participants regarding Appendices E1 and E2, please submit draft letters to the NIOSH HSRB for review along with a request for an amendment (CDC form: 0.1252 + 0.1379 (signature page), and 0.1370 (collaborators/partners).

Additionally, for collaborator, American Lung Association of Maine, please contact Kathy Masterson of the NIOSH HSRB Office to discuss this collaborator's role in this protocol to ensure the necessary agreements are in place.

Protocol Issues – None.
Consent Form Issues – None.
Addenda Issues (Scripts, questionnaires, brochures, etc.)– None.

End of report

Kathy Masterson for Cherie Fairfield Estill, M.S., P.E.

cc:
HSRB 08-DRDS-01

New Protocol

0.1379

Centers for Disease Control and Prevention
NIOSH HSRB

Date received
2/4/08

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 08-DRDS-01.* Protocol version number version date

Protocol title: Leveraging Implications of Building-Related Asthma Research in Public Schools

Amendment number (if applicable):

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Jean Cox-Ganser, PhD	jjc8	2692	NIOSH/DRDS
Principal investigator (required)	Jean Cox-Ganser, PhD	jjc8	2692	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:	1/29/2008	

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:	1/29/08	Check if PI is Team Lead: ☒
Branch Official (e.g., Chief or Senior Scientist):	1/29/08	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS):	2/1/08	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	Date	Remarks
Chair, NIOSH HSRB:	4-18-08	APPROVED
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		Full board received and approved. Continuing reviews will be done on an expedited basis.

5 Additional comments

Full board 3/11/08 & 4/8/08 reviews

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.