Attachment 9: Institutional Review Boards

Asthma Education Study

November 17, 2011

Project Officer: Scott A. Damon, MAIA, CPH, RPCV
Centers for Disease Control and Prevention
National Center for Environmental Health
Division of Environmental Hazards and Health Effects
Air Pollution and Respiratory Health Branch

MEMORANDUM

Oak Ridge Site-wide Institutional Review Board (ORSIRB)
Telephone (865) 576-1725 Facsimile (865) 576-9557
Becky.Hawkins@orise.orau.gov

MEMORANDUM

DATE:	March 14, 2011
TO:	Richard Tardif, Ph.D.
FROM:	Oak Ridge Site-Wide IRB (FWA #00005031)
STUDY TITLE:	[221586-1] Asthma Education Study
IRB REFERENCE #:	ORAU EX(11)-9
SUBMISSION TYPE:	New Project
ACTION:	DETERMINATION OF EXEMPT STATUS
DECISION DATE:	March 14, 2011

Thank you for your submission of New Project materials for this research study. The Oak Ridge Site-Wide IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations as outlined in 45 CFR 46.101(b)(2). Waiver of documentation of informed consent is approved as outlined in 45 CFR 46.117(c).

We will put a copy of this correspondence on file in our office and get in touch with you in approximately a year to determine if this project is still ongoing or if any changes have occurred that would change this exemption status.

If you have any questions, please contact Becky Hawkins at 865-576-1725 or becky.hawkins@orise.orau.gov. Please include your study title and reference number in all correspondence with this office.

cc: D. McFalls

Memorandum

Date April 26, 2011

From Barbara R. DeCausey, MPH, MBA
Chief, Human Research Protection Office

Subject HRPO Exemption Determination for Protocol #6100.0, "Asthma Education Study"

To Scott Damon
NCEH/EHHE

On behalf of the CDC Human Research Protection Office (HRPO), I have reviewed the request to exempt protocol #6100.0, “Asthma Education Study" and find that this research activity is exempt under 45 CFR 46.101(b)(1) and (2). This determination is valid for a period of three years through **04/25/2014.** However, we strongly encourage investigators to close out exempt protocols as soon as CDC staff are no longer engaged in the research activity, rather than waiting for a reminder of the three-year expiration date.

Please be aware that changes to this protocol may not be implemented until they are reviewed by HRPO and determined to be consistent with the exemption categories. You will be reminded in three years (if the study has not been completed and closed) to submit another request for continuation and to confirm that no changes have been made to the protocol or the related science that would affect the ethical appropriateness of the research or this exemption determination.

Please also be advised that investigators remain responsible for the ethical conduct of this study and for ensuring appropriate human research protections even for research that is exempt from the regulations governing the protection of human subjects in research.

If you have questions, please contact your Division Associate Director for Science, your National Center Human Subjects Contact, or HRPO at huma@cdc.gov, or by telephone at 404-639-4721.

cc:
NCEH/ATSDR Human Subjects