-----Original Message-----
From: Peterson, Felecia (CDC/OD/OCSO)
Sent: Wednesday, September 05, 2007 4:31 PM
To: Brown, Mary Jean (CDC/CCEHIP/NCEH)
Cc: NCEH/ATSDR Human Subjects (CDC); Latimer, Annie (CDC/CCEHIP/NCEH); Herbert, Arnetra R. (CDC/CCEHIP/NCEH); Lawton, Kay E. (CDC/CCID/NCZVED)
Subject: 4064: IRB Approval of Continuation of Protocol , (Expedited)

DATE: 9/5/2007

FROM: IRB Administrator
Human Research Protection Office
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Continuation of Protocol #4064, "Public Health Research Using Data Collected for Child Blood Lead Surveillance" (Expedited)

TO: MARYJEAN BROWN, ScD, RN [MJB5]
NCEH/EEHS

CDC's IRB "G" has reviewed and approved your request to continue protocol #4064 for the maximum allowable period of one year and it will expire on 10/23/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Category 8(c). Study is not designed to involve research-related contact with participants (e.g., research using existing records); study activities involve only access to or analysis of data or biological specimens and writing reports.

If other institutions involved in this protocol are being awarded CDC 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 that 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. 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 at least six weeks before the protocol's expiration date of 10/23/2008.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639-4721 or e-mail: huma@cdc.gov.

Felecia Peterson

cc:
NCEH/ATSDR Human Subjects (CDC)
Annie Latimer
Arnetra Herbert
Kay Lawton

Public Health Research Using Data Collected for Child Blood Lead Surveillance Protocol

August 29, 2007

Prepared by

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Table of Contents

I. PROJECT OVERVIEW

Title: ***Public Health Research Using Data Collected for Child Blood Lead Surveillance***

A. Summary

Lead is neurotoxic and particularly harmful to the developing nervous systems of fetuses and young children. Extremely high blood lead levels (BLLs) (i.e., ≥70 micrograms of lead per deciliter of blood [µg/dL]) can cause severe neurologic problems (e.g., seizure, coma, and death). However, no threshold has been determined regarding lead's harmful effects on children's learning and behavior, which is observed at lower BLLs. The U.S. Department of Health and Human Services established a national goal to eliminate BLLs ≥10 µg/dL in children aged <6 years by 2010. CDC's grants program supports state and local childhood lead poisoning prevention programs (CLPPPs).

All state and local CLPPPs collect surveillance data; some CLPPPs have more than 10 years of data. CLPPPs send their surveillance data to CDC annually. The child blood lead surveillance (CBLS) database that CDC maintains has blood lead test results for approximately 14.5 million children aged < 72 months, the age group which is the focus of the CLPPP. Each child record contains demographic and laboratory test information. Records for children with moderate to high BLLs (≥ 15 g/dL) may include environmental and risk assessment information. These data represent a rich source of data that can be used to examine issues of public health importance. Examples include identifying factors related to decreasing children's BLLs, such as differences in state and local CLPPPs screening policies, case management and program practices; and the contribution of multiple lead sources on children's blood lead levels.

This protocol describes our plans to conduct a series of studies over the next five years using existing routinely collected surveillance data to provide information to help reduce children's BLLs. The purpose of this protocol is to facilitate analysis of child blood lead surveillance data A variety of issues related to preventing elevated BLLs will be examined. Although names and addresses are not included in CDC's state-collected surveillance data, these data contain unique identification numbers for each child and address that can be used to assess factors that influence changes in children's BLLs over time. We are requesting a waiver of informed consent because the unique identification numbers could be linked back to the child at the state or local CLPPP, however, it would not be possible to obtain consent on data collected up to ten years ago. The intended uses of the findings from these studies are to share what we learn with CLPPPs and policy makers so that this information can be used to improve screening plans, better direct resources and accelerate progress towards elimination of childhood lead poisoning.

B. Investigators and Collaborators

This proposal is intended to serve as a blanket protocol for analysis of existing, routinely collected child blood lead surveillance data to answer questions of public health importance. All such public health research will have an NCEH Principal Investigator (PI). The PI will be responsible for designing the study and overseeing analysis, writing and dissemination of findings. Co-investigators may include scientific staff from the CDC Lead Poisoning Prevention Branch (LPPB) and state and local CLPPP depending on contribution to design, analysis and writing of the study. When there are investigators who are not currently in LPPB and are not CLPPPs, an NCEH PI will be designated.

Mary Jean Brown, ScD, RN	Principal NCEH investigator. Develop the study design, analysis, writing and publications.
LPP Branch staff	Co-investigators. Provide expert insight into all aspects of the study, study design, data analysis and report writing.
State/local grantees	Consortium with states to develop data fields collected and they submit their data to CDC and at times as co-investigators.

II. INTRODUCTION

A. Background

Exposure to lead can damage the nervous, hematopoietic, and renal systems (*1*,*2*) and is particularly harmful to the developing nervous systems of fetuses and children aged <72 months. Extremely elevated blood lead levels (BLLs) ≥70 micrograms of lead per deciliter of blood (µg/dL) can cause severe neurologic problems (e.g., seizure, coma, and death) (*3*). Although severe cases are rare today (*4*), the threshold for harmful effects of lead remains unknown. Studies since the late 1980s have linked BLLs as low as 10 µg/dL with decreased intelligence and other adverse neurodevelopmental effects (5-*8*) motivating CDC to lower the level of concern for children aged < 72 months to BLLs 10 µg/Dl in 1991 (9). Subsequent studies provided evidence of adverse effects at even lower levels, <10 µg/dL, among children aged <72 months (*10–14*).

CDC funds state and local programs to build capacity and develop childhood lead poisoning prevention programs and surveillance activities at the state and local levels. The objectives of these childhood lead poisoning prevention programs (CLPPPs) are to 1) screen infants and children for elevated BLLs; 2) ensure that lead-poisoned infants and children are referred for medical and environmental intervention; 3) educate the public and health-care providers about childhood lead poisoning; and 4) carry out prevention activities to reduce children=s exposure to lead. DHHS established a Healthy People 2010 goal to eliminate elevated BLLs (i.e., BLLs 10 µg/dL) among children aged 1 - 5 years (15). Because lead will be eliminated primarily through state and local prevention efforts, state and local data are necessary to evaluate, improve and effectively target prevention activities and to monitor progress at the state and local levels.

B. General Approach

The public health research covered under this protocol will use existing data collected for routine surveillance of children's BLLs to address specific questions of public health importance that will help achieve the goal of eliminating BLLs 10 g/dL by 2010. We plan to:

1) Describe the state/local burden of BLLs ≥ 10 g/dL among young children;
2) Assess progress toward elimination of BLLs ≥ 10 g/dL among young children;
3) Define characteristics of children with BLLs ≥ 10 g/dL by region and state;
4) Assess associations between case management practices and interventions and children's BLLs;
5) Improve case management, program practices, and surveillance;
6) Assess the impact of state and local policies on reducing children's exposure to lead in their environment.
7) Assess environmental inspection and remediation activities;
8) Identify sources of exposure and compare across different regions;
9) Focus national, state and local attention on the goal of eliminating elevated BLLs by 2010.

III. METHODS

A. Design

1. How surveillance system meets objectives

The surveillance data contain demographic and laboratory information on all children reported by CLPPPs. Environmental and risk assessment information is available for children with moderate to high BLLs (15 g/dL). Sequential specimens allow researchers to follow children over time to assess factors associated with changes in BLLs. In addition, knowledge of state/local policies and case management and program practices allows researchers to assess the impact of policies and practices on children's BLLs.

2. Audience and stakeholder participation

The audience is the childhood lead poisoning prevention programs and others interested in reducing children's blood lead levels. The stakeholders are the childhood lead poisoning prevention programs.

B. Study Population

1. Source of study population

All states with CDC-funded childhood lead poisoning prevention programs must collect surveillance data and submit it to CDC. State and local childhood lead surveillance systems are based on the results of blood lead tests reported to state health departments by private and public laboratories. State and local laws and regulations establish the BLL that is reportable. Core data variables are collected on every child tested depending on the child's blood lead level. For example, children with blood lead levels < 10 g/dL may

only have information on demographics and laboratory tests. Those with blood lead levels ≥ 25 g/dL may have information on address and remediation activities.

When states submit their surveillance data to CDC, they remove child identifiers such as name and address and replace them with unique identification numbers. Because these unique identifiers can be linked back to a child's name and address at the state health department, CDC will replace the unique identifiers with randomly assigned numbers to protect confidentiality. A list of the fields that CDC collects are shown in Appendix A. The data variables include identifying demographic information, such as the tested child=s race/ethnicity and date of birth, and laboratory information, such as type of specimen (venous or capillary blood), date of specimen collection, and test result.

2. Case definitions

Elevated BLLs (cases) are defined as BLLs ≥ 10 g/dL. A confirmed elevated BLL is one venous blood specimen 10 µg/dL, or two capillary blood specimens 10 µg/dL drawn within 12 weeks of each other. Unconfirmed elevated BLLs are single capillary tests 10 µg/dL. Some researchers may analyze data using confirmed, unconfirmed or both confirmed and unconfirmed elevated BLLs as cases.

3. Participant inclusion criteria

Young children (i.e., < 72 months of age) are the focus of the childhood lead poisoning prevention programs because they are most vulnerable to health damage from lead and there is a national goal to eliminate BLLs ≥ 10 g/dL among children aged < 72 months

by 2010.

4. Estimated number of participants

The child blood lead surveillance database that CDC maintains has blood lead test results for 14,468,252 children aged < 72 months. The number of children in this database should allow adequate sample sizes to address various research questions.

5. Request for Waiver for Informed Consent

A waiver of informed consent is requested, under 45 CFR 46.116(d). The large number of potential subjects and the time that has elapsed since the data was collected makes obtaining consent from the potential subjects impracticable. Furthermore, there is no harm to subjects because we will only collect information from existing routine surveillance records and the information collected will not be of a sensitive nature.

(1) The research involves no risk to the subjects. We will analyze information from existing surveillance records. The information collected will include minimal demographic information, dates of laboratory tests and in some cases dates of environmental inspections. A unique identification number for each child is used to link various records: laboratory, environmental investigation, child demographics and address identification number. We will replace these unique identification numbers with randomly generated numbers so records cannot be linked back to a child at the state health department.

(2) This waiver will not adversely affect the rights and welfare of the subjects. The information collected is not of a sensitive nature. Information on individuals will

not be released. Only aggregate results will be reported.

(3) Since we will analyze information using existing surveillance records collected several years ago, we may be unable to locate many of the children in the surveillance database. Trying to locate all the children in the surveillance database could delay the study, increase cost and introduce selection bias making the conduct of this study impracticable without the waiver of informed consent.

(4) Our findings will be distributed to the lead poisoning prevention community and stakeholders through reports, scientific publications, and presentations at scientific and grantee meetings.

C. Variables

The list of core variables that state and local CLPPPs submit to CDC is shown in Appendix A. The variables include child demographic information, laboratory test results and test dates, address information and environmental inspection information for some children.

D. Data Handling and Analysis

Several different study designs and analyses may be used depending on the specific objectives. Since each child has a unique identifier, it is possible to follow children over time to assess factors that affect changes in BLLs. Descriptive statistics can be calculated to determine the range of blood lead levels. In addition, blood lead levels will be examined by age, sex, race, and geographic location, and look for trends over time. **All information will be kept confidential. The dataset that CDC will have for analysis in Atlanta will contain no person identifiers. CDC investigators will make no attempt to link data to identifiers held by the states**

E. Handling of unexpected or adverse events

The surveillance database that CDC maintains has no children's names or addresses, however CDC has unique child identification numbers and address identification numbers that the state and local CLPPPs have assigned. Although the state and local CLPPPs remove names and addresses before they send the data to CDC, the identification numbers that CDC has could be used to identify individual children and addresses by linking them with the state and local databases that still contain children's names and addresses. To prevent linking with individual children and specific addresses, CDC will replace the unique child and address identification numbers with randomly generated numbers. There is always the potential for losing data through disk corruption and to prevent losing data. To ensure that data is not completely lost, copies will be made and kept on CDC premises.

F. Limitations

The surveillance data is not a representative sample. In addition, the surveillance data probably underestimate the number of children tested and the number of children with BLLs ≥ 10 g/dL. Not all children at risk are tested. Testing recommendations and practices vary across the country. Because today most children with elevated BLLs are asymptomatic, the only way to know if a child has an elevated BLL is to perform a blood lead test. Clinicians who rely on risk assessment questions to identify for testing children who are most likely to have elevated BLLs, may miss children who are truly at risk. States that don't test children at highest risk may have surveillance data that under represents the number of children with elevated BLLs. For some analyses it may not be possible to use certain fields such as race if there is a lot of missing data.

Similarly, some states do not submit complete environmental inspection data.

G. Dissemination and reporting of results

Only aggregate findings will be reported. All data sets, summary reports, and papers produced from these studies using surveillance data will *not* include any individual identifying information. The findings may be published in medical journal, reports or as summaries prepared for the public.

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APPENDIX A

Surveillance Fields CDC Collects from State CLPPPs

Record Type: Basic Format

Field Name	Valid Values – Description
fileid	File identifier for record type. ADD - address data CHI - child INV - investigation LAB - lab LNK - child to address link
action	Database action code. A - add record C - change/replace D - delete
qtr	Reporting quarter. All annual submissions should be “4" for fourth quarter. 1 - first quarter (1/01/yy - 3/31/yy) 2 - second quarter (4/01/yy - 6/30/yy) 3 - third quarter (7/01/yy - 9/30/yy) 4 - fourth quarter (10/01/yy - 12/31/yy)
rpt_yr	Reporting year. Last two digits of the reporting year. (Must be numeric.)
pgmid	Program identifier. A unique identifier for the CLPPP (or lead database) submitting the data. The first two position must contain the state FIPS (Federal Information Processing Standard) code. The next three positions are preassigned for STELLAR databases and must be unique for each lead database within a state (including databases other than STELLAR).
child_id	Child identifier. A unique identifier for a child; must be numeric and zero-filled. This would generally be a system-assigned sequential number within a database. The identifier is used in relational databases to eliminate redundant data. The child information exists only once, in one physical record, and is linked to related records by the child identifier. When records from two or more databases are combined, the combination of pgmid and child_id form a unique identifier within the combined database.

addr_id	Address identifier. A unique identifier for an address; must be numeric and zero-filled. This would generally be a system-assigned sequential number within a database. The identifier is used in relational databases to eliminate redundant data. The address information exists only once, in one physical record, and is linked to related records by the identifier. When records from two or more databases are combined, the combination of pgmid and addr_id form a unique identifier within the combined database.
all_the_rest	A variable format area. The contents and format depend on the value in the field fileid.

Record Type: Address
FileId: ADD

Field Name	Valid Values -– Description
	Basic format as illustrated in Table 1. REQUIRED
addr_id	See Table 1. REQUIRED
city	City name.
cnty_fips	County FIPS code. REQUIRED Numeric, zero-filled. A file of counties and assigned FIPS codes is available from Lead Poisoning Prevention Branch.
zip	Zip code (5+4 format, no dash). Left justified, blank-fill or zero-fill.
state	State abbreviation.
census	Census tract. Left justified, blank-fill.
renovated	Residence renovated? 1 - yes, once 2 - no 3 - yes, more than once 9 – unknown
start_ren	Date first renovation begun. (CCYYMMDD) Date must be present when renovated field (col 57) is coded 1 or 3. Date must be blank when renovated field is coded 2 or 9.
comp_ren	Date latest renovation completed. (CCYYMMDD) Cannot be earlier than start_ren date. Leave blank if renovation is ongoing as of the end of the reporting year.

Record Type: Child
FileId: CHI

Field Name	Valid Values – Description
	Basic format as illustrated in Table 1. REQUIRED
child_id	See Table 1. REQUIRED
dob	Child's date of birth. (CCYYMMDD) REQUIRED Birth date cannot be after the end of the reporting year. Child may not be older than 16 years at the start of the reporting year.
gender	1 – male 2 - female 9 – unknown
race * Multi-racial and Other codes will be eliminated after the 2001 data submission in accordance with OMB guidelines.	

Race	**Code**
American Indian or Alaskan Native	1
Asian	2
Black or African American	3
Native Hawaiian or Other Pacific Islander	5
White	4
Unknown	9
* Multi-Racial	7
* OTHER	8
American Indian or Native Alaskan/Asian	A
American Indian or Native Alaskan/Black	B
American Indian or Native Alaskan/Native Hawaiian or Other Pacific Islander	C
American Indian or Native Alaskan/White	D
Asian/Black	E
Asian/Native Hawaiian or Other Pacific Islander	F
Asian/White	G
Black/Native Hawaiian or American Indian	H
Black/White	I
Native Hawaiian or Other Pacific Islander/White	J
American Indian/Asian/Native Hawaiian	K
American Indian/Black/Native Hawaiian	L
American Indian/Asian/Black	M
American Indian/Asian/White	N
American Indian/Black/White	O
American Indian/Native Hawaiian/White	P
Asian/Black/Native Hawaiian	Q
Asian/Black/White	R
Asian/Native Hawaiian/White	S
Black/Native Hawaiian/White	T
American Indian/Asian/Black/White	U
American Indian/Black/Native Hawaiian/White	V
Asian/Black/Native Hawaiian/White	W
Black/American Indian/Asian/Native Hawaiian	X
Native Hawaiian/American Indian/Asian/White	Y
American Indian/Asian/Black/Native Hawaiian/White	Z

sp_ethn	Race/Ethnicity (this field may be left blank) I - Asian Indian J - Japanese C -Chinese S - Samoan F - Filipino G - Guamian H - Hawaiian M - Hmong K - Korean O - Other V - Vietnamese Z - Unknown
ethnic	1 – Hispanic 2 - Non-hispanic 9 - Unknown
chelated	1 - Yes 2 - No 9 - Unknown
chel_type	1 - Inpatient 3 – Both 2 - Outpatient 9 - Unknown Cannot be blank if chelated field =1. Cannot be 1, 2 or 3 if chelated =2 or 9.
fund_source	1 - Public, includes Medicaid 8 - Other 2 - Private insurance 9 - Unknown 3 - Parent self-pay Cannot be blank if chelated field = 1 or 9.
nplsz	Non-paint lead source - other. 1 - Yes 2 - No 9 - Unknown
nplsm	Non-paint lead source - traditional medicines. 1 - Yes 2 - No 9 - Unknown
nplso	Non-paint lead source – occupation of household member. 1 - Yes 2 - No 9 - Unknown
nplsh	Non-paint lead source - hobby of household member. 1 - Yes 2 - No 9 - Unknown
nplsp	Non-paint lead source - pottery, imported or improperly fired 1 - Yes 2 - No 9 - Unknown
nplsc	Non-paint lead source - child occupation. 1 - Yes 2 - No 9 - Unknown

Field Name	Valid Values – Description
	Basic format as illustrated in Table 1. REQUIRED
addr_id	See Table 1. REQUIRED
date_ref	Date address referred for investigation. (CCYYMMDD) REQUIRED
insp_comp	Date address investigation inspection completed. (CCYYMMDD) May not be prior to date_ref.
abat_comp	Date address hazard remediation or abatement completed. (CCYYMMDD) May not be prior to insp_comp.
year	Year the dwelling was constructed. (YYYY) Blank if unknown. May not be after reporting year.
ownership	1 - Private, owner-occupied 2 - Rental, privately owned 3 - Rental, publicly owned 4 - Rental, Section 8 9 - Unknown
dwell_type	1 - Attached, single family 2 - Day care center 3 - Detached, single family 4 - Multi-unit 5 - School 8 - Other 9 - Unknown
paint_haz	Dwelling with peeling, chipping, or flaking paint. Must be 9 if insp_comp is blank. 1-Yes, interior 2-Yes, exterior 3-Yes, both 4 - No 9 - Not inspected
xrf	Highest XRF reading in mg/cm^2. (000.0) See Note below.
dust_floor	Highest floor dust sample reading. (000000.0) See Note below.
floor_msr	Unit of measure. U - μg/ft^2 Cannot be blank if dust_floor >0. P – ppm
dust_sill	Highest window sill dust sample reading. (000000.0) See Note below.
sill_msr	Unit of measure. U - μg/ft^2 Cannot be blank if dust_sill >0. P – ppm
dust_well	Highest window well dust sample reading. (000000.0) See Note below.
well_msr	Unit of measure. U - μg/ft^2 Cannot be blank if dust_well >0. P – ppm
paint	Highest paint chip sample reading. (000000.0) See Note below.
paint_msr	Unit of measure. U - μg/ft^2 Cannot be blank if paint >0. P - ppm M - mg/cm^2
soil	Highest soil sample reading in ppm. (000000.0) See Note below.
water	Highest water sample reading in ppb. (000000.0) See Note below.
indhaz	Industrial hazard near dwelling. 1 - Yes 2 - No 9 - Unknown

Note: Environmental sample results should all be shown right-justified, zero-filled on the left, and formatted with one decimal position. If no decimal value, format with decimal and zero (000500.0).

Record Type: Lab Results
FileId: LAB

Field Name	Valid Values – Description

	Basic format as illustrated in Table 1. REQUIRED
child_id	See Table 1. REQUIRED
samp_date	Date sample was drawn. (CCYYMMDD) REQUIRED May not be prior to child date of birth.
addr_id	Unique identifier of child's primary address on the date sample was drawn. (See Table 1.) Zero-fill if unknown.
result	Sample result measured in μg/dL. Whole number, zero-filled. REQUIRED
fund_source	Source of funding for the test. 1 - Public, includes Medicaid 2 - Private insurance 3 - Parent self-pay 8 - Other 9 – Unknown
samp_type	Sample type. 1 - Venous, blood lead 2 - Capillary, blood lead 9 - Unknown
test_rsn	Test reason. 1 - Screening (asymptomatic child withou previous elevated level) 2 - Clinical suspicion of lead poisoning (child symptomatic) 3 - Confirmatory test following elevated value by fingerstick 4 - Follow-up, child with confirmed elevated level 5 - EP, not for lead-screening * 9 - Unknown/other
lab_type	Type of laboratory processing sample. 1 - Public health laboratory 2 - Commercial laboratory 9 - Unknown
scrn_site	Type of provider ordering test, or screening site. 1 - CLPPP fixed-site specific to lead 2 - Door to door program 3 - Other fixed-site screening program, e.g. WIC 4 - Private health care provider 5 - Referred for confirmation, no screening information 9 - Unknown/other
medicaid	1 – Yes 2 - No 9 – Unknown
samp_anaz_dt	Date sample analyzed by lab. (CCYYMMDD) May not be prior to samp_date.
rslt_rpt_dt	Date results reported to/received by health department. (CCYYMMDD) May not be prior to samp_date.

Record Type: Child to address link (Optional record type)
FileId: LNK

Field Name	Valid Values – Description
	Basic format as illustrated in Table 1. REQUIRED
child_id	Unique child identifier. See Table 1. REQUIRED
addr_id	Unique address identifier. See Table 1. REQUIRED
type_addr	1 - Primary address 2 - Relocation address 3 - Alternative 4 - Supplemental 9 – Unknown
first_occ	Date the child first occupied or began spending time at address. (CCYYMMDD) REQUIRED May not be after the end of the reporting period.
last_occ	Date the child moved from or ceased spending time at address. (CCYYMMDD) May not be prior to first_occ date.

NOTE: There should be only one "open" link record per child (last_occ is blank) where address type code is **1** or **2**. A relocation address is considered a primary address to which a child has been permanently moved to remove them from a hazardous environment.