# Request for Continuing Review of Exempted Protocol

Use this form to submit a protocol for continuing review of a protocol that HRPO has deemed exempt from human subjects regulations. See *HRPO Guide: Exempt Review Cycle* for further details on how to complete this form.

## 1 Protocol identifiers

CDC protocol ID: 4064 Protocol version number 2 version date 08/29/2007

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

## 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 | SEV # | CDC NC/division |
|---|---|---|---|---|
| Primary contact (required) | Mary Jean Brown, ScD, RN | mjb5 | 4630 | NCEH/EEHS |
| Principal investigator (required) | Mary Jean Brown, ScD, RN | mjb5 | 4630 | NCEH/EEHS |
| Investigator 2 | | | | |
| Investigator 3 | | | | |
| Investigator 4 | | | | |
| Investigator 5 | | | | |

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.

List all other CDC investigators, if any. Include name and degrees, user ID, SEV #, CDC NC/division:

## 3 CDC's research partners

Research partners include *all* direct and indirect recipients of CDC funding (e.g., grants, cooperative agreements, contracts, subcontracts, purchase orders) and other CDC support (e.g., identifiable private information, supplies, products, drugs, or other tangible support) for this research activity, as well as collaborators who do not receive such support. On continuing review, HRPO needs current information on partners that have been added or dropped since the last review and partners that, as of the last review, were receiving support for nonexempt research. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☒ No research partners are reported with this submission. (This may occur because there are no partners, or because no partners are being added, or because no previously reported partners are still both supported by CDC and engaged in nonexempt research.)

☐ Research partners are listed on form 0.1370, which accompanies this form.

# 4 Study participants—cumulative demographic frequencies

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

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites. See *HRPO Guide: Exempt Review Cycle* for definitions.

| | |
|---|---|
| Number of participants | 3,000,000 |
| Location of participants | |
| Participating at domestic sites | 3,000,000 |
| Participating at foreign sites | 0 |
| Sex/Gender of participants | |
| Female | 1,000,000 |
| Male | 1,000,000 |
| Sex/gender not available | 1,000,000 |
| Ethnicity of participants | |
| Hispanic or Latino | 300,000 |
| Not Hispanic or Latino | 1,000,000 |
| Ethnicity not available | 1,700,000 |
| Race of participants | |
| American Indian or Alaska Native | 50,000 |
| Asian | 50,000 |
| Black or African American | 1,000,000 |
| Native Hawaiian or Other Pacific Islander | 50,000 |
| White | 1,000,000 |
| More than one race | 10,000 |
| Race not available | 2,160,000 |

Comments on demographics

# 5 Study status

## 5.1 Participant involvement

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

☒ 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.

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

- ☐ Contact with participants has not yet begun.
- ☐ Contact with participants has begun and continues.
- ☐ Contact with participants is completed; study activities involve only data analysis or report writing.

## 5.2 Overall study conduct

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.

No research analyses have been conducted due to lack of resources. However, we do intend to implement this when resources can be dedicated to this.

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. (Proposed changes should be submitted to HRPO for review before they are implemented, so that it may be determined if the study remains exempt. Use form 0.1252X.)

None

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

None

Summary of incidents and other substantial concerns since last continuation.

None

Summary of remaining research activities.

None

## 6 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.

- ☒ 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 research partners (required only for partners being added or for supported/nonexempt partners)
- ☐ Progress and monitoring reports (recommended when available)

## 7 Additional comments