OMB #: 0925-0647
Expiration Date: 01/31/2015

NCS Formative Research Template for OIRA Clearance

TO BE COMPLETED BY STUDY CENTER:

LOI #: LOI - [ ] - BIO - 0

Title of Formative Research: Analysis of Chemicals in Dried Blood Spots

Participating Institutions: **Greater Chicago Study Center**

Recruitment Study Arms: **Enhanced Household; Two-Tier High-Low; Provider Based**

SME: Jack Moye

COTR: Kate Winseck

Purpose of the Study: To develop a method to measure children's exposure to environmental toxins using biological determinants of health that can be found in dried blood spots taken from finger prick or heel stick blood samples. This study will explore the effectiveness of analyzing toxins in a dried blood spot compared to venipuncture and will examine the content of heavy metals and PAH-protein adducts in 100 children in the Greater Chicago area. For more information, please see pages 1 and 2 of the protocol description.

Benefit to NCS Vanguard or Main Study: This study will examine a less invasive and more cost-efficient method of assessing the presence of toxins in children's blood compared to venous blood draws which are typically used. If robust, this method will decrease cost and participant time. For more information, please see page 3 of the protocol description.

Study Design: For each child recruited into this pilot study, we will collect: 1) a finger or heel stick of approximately five drops of blood on a Whatman 903 Protein Saver Card, and 2) an extra 10 mL lavender top tube of blood on a current blood draw. Each pilot study participant or parent/guardian will fill out a 2-question survey asking for his/her age and sex. The blood spots and blood draws will be analyzed for toxins and the efficacy of each method. Please see page 2 of the protocol description.

Target Respondents: This pilot study will recruit 100 children demographically similar to, but not geographically eligible for the NCS Vanguard Study, ages 0 months to 21 years, for this substudy. The eligibility criteria for this substudy are broad so that the enrollment targets can be met quickly and conveniently. Infants will not specifically be enrolled in this substudy, though they may be included. We anticipate that more older children will be enrolled in this substudy than infants. The parent / legal guardian will provide consent for the child's participation and respond to the brief questionnaire in cases where the child is not old enough to respond. Please see page 2 of the protocol description for more information.

Sample Size Calculation: For methods validation it is important to have a range of physiological values in the samples we collect that represents the full range of values we expect to see when the methods are applied. Based on our prior methods validation work, we have found that a sample size of 100 is large enough to capture this full range of variation. A smaller sample size risks having few, if any observations at the extremes of the distribution, thereby compromising our ability to validate the methods.

Method of Recruiting: Non-NCS Vanguard participants will be recruited as a convenience sample for this research project. Patients at the Children's Memorial Hospital (CMH) Outpatient Center Laboratory will be invited to participate in this substudy. A Northwestern University research assistant will recruit and consent participants when they come for previously-scheduled blood draws in the Outpatient Center Laboratory. Because the recruitment will be conducted at an outpatient clinic of CMH, CMH nurses from their Clinical Research Unit may provide support and will be compensated for all of their time. The Greater Chicago Study Center has an agreement in place whereby CMH staff are compensated for support provided to assist Study Center functions. Since participants will be recruited at regularly-scheduled blood draw visits, we will not use any additional recruitment materials such as fliers or brochures. Enrollment will continue until project-specific recruitment targets have been reached. Please see page 2 of the Research Plan attachment.

NCS Formative Research Template for OIRA Clearance

***Confidentiality:** Study Centers must abide by the terms of their Data Use Agreement, which should reference all formative research efforts involving the collection or management of NCS restricted-use data. All participating Study Centers will have approved Data Use Agreements and Security Plans prior to launch.

***IRB Approval:** Local IRB clearance for this activity has been obtained by the participating Study Center. Please see the attached IRB approval letter.

Incentives: Subjects will be compensated following the venous blood draw and finger prick/heel stick. The incentives will be age-appropriate: 1) for young children, a small toy and a $10 gift card; or 2) for older children, a $15 gift card. The total value of both types of incentives is $15.

Sensitive Questions: We will not ask sensitive questions as a component of this study.

Proposed Project Schedule: We will begin this project upon receipt of all regulatory approvals.

Data Collection Burden:

Estimates of Annual Hour Burden -- Generic Substudy: LOI3-BIO-0, "Analysis of Environmental Chemicals in Dried Blood Spots"

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours
Informed Consent	Parent / Legal Guardian	100	1	0.17	17
Child Assent	Child	100	1	0.08	8
Brief Questionnaire	Parent / Legal Guardian / Child	100	1	0.03	3
Biospecimen Collection	Child (age 0-21)	100	1	0.08	8
TOTAL		200			36

Annualized Cost to Respondents -- Generic Substudy: LOI3-BIO-0, "Analysis of Environmental Chemicals in Dried Blood Spots"

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Hourly Wage Rate	Respondent Cost
Informed Consent	Parent / Legal Guardian	100	1	$10.00	$170.00
Child Assent	Child	100	1	$10.00	$80.00
Brief Questionnaire	Parent / Legal Guardian / Child	100	1	$10.00	$30.00
Biospecimen	Child (age	100	1	$10.00	$80.00

* To be completed before project proposal is submitted for OIRA clearance.

Collection	0-21)				
TOTAL		200			$360.00

☒ **Please check here after ensuring that all calculations have been verified**

Estimated Costs: Staff Hours: 72 hours.
Supervisor Hours: 18 hours.

Attachments: Informed Consent for Adult, Informed Consent for Parents/Guardians, Child Assent, Brief Questionnaire, Protocol Description, Biospecimen Sample Processing Protocol, IRB Approval Letter. Note: All materials have been approved by the local IRB prior to use.

☒ **Please check here after ensuring that the OMB #: 0925-0647 and Expiration Date: 1/31/2015 date have been inserted as first-page headers on each proposed instrument.**

☒ **Please check here after ensuring that the following OMB burden statement has been inserted as a first-page footer on each proposed instrument.**

Public reporting burden for this collection of information is estimated to average [SC insert estimated response time] minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0647*). Do not return the completed form to this address.

Appendix 1. Maximum NCS Incentives, by Study Activity and Impact on Participants (Approved by OMB 1/5/12)

Data Collection Activity Characteristics	Initial NCS Vanguard Study	NCS Recruitment Substudy and Formative Research		
		Phase 1	Phase 2	Formative Research
Time for encounter	3 hours	0.5 to 1 hour	0.5 to 1 hour	0.5 to 1 hour
Sensitivity of questions	Sensitive, including sexual activity	Few sensitive questions	Few sensitive questions	Few sensitive questions
Physical measures	Yes	No	No	Yes*
Environmental specimens	Yes	No	Yes	Yes*
Biospecimens	Yes	No	Yes	Yes*
Participant observation	Yes	No	No	No
Monetary incentive, per visit	$100	$25	$25 for the group of study questionnaires, plus $25, in total, for any bio-specimens collected during a contact and, where appropriate for environmental specimens	$25, in total, for any bio-specimens collected during a contact. For questionnaires, or any environmental specimens – up to $25 when deemed necessary
Non-monetary incentives (tote bags, post its, key chains, etc.)	In addition to the monetary incentive, non-monetary incentives valued at $25 or less may be offered to participants	As an alternative to the monetary incentive, NCS logo gifts valued at $25 or less may be offered to the participants in lieu of cash or local incentives not exceeding $25 in value and deemed non-coercive by local IRBs	In addition to the monetary incentive, NCS logo gifts valued at $25 or less may be offered to the participants if these are deemed acceptable by local IRBs	Instead of monetary incentives, NCS logo gifts valued at $25 or less may be offered to the participants if these are deemed acceptable by local IRBs