# Appendix C

# Additional Study Documentation

# Appendix C.1

# Legal Authority

Children's Health Act of 2000 (Public Law 106-310 Sec. 1004).

Congress authorized the planning and implementation of the National Children's Study with the Children's Health Act of 2000 (Public Law 106-310 Sec. 1004).

**SEC. 1004. LONG-TERM CHILD DEVELOPMENT STUDY.**
(a) PURPOSE—It is the purpose of this section to authorize the National Institute of Child Health and Human Development to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.
(b) IN GENERAL—The Director of the National Institute of Child Health and Human Development shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—
(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.
(c) REQUIREMENT—The study under subsection (b) shall—
(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;
(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and
(3) consider health disparities among children, which may include the consideration of prenatal exposures.

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# Appendix C.2

# Hypotheses Topics

**Hypotheses Topics of the National Children's Study**

- Birth defects from impaired glucose metabolism
- Increased risk of preterm birth from intrauterine exposure to mediators of inflammation
- Increased risk of fetal growth restriction, preterm birth, birth defects and developmental disabilities in children born through assisted reproductive technologies
- Maternal subclinical hypothyroidism and neurodevelopmental disabilities/adverse pregnancy outcomes
- Non-persistent pesticides and poor neurobehavioral and cognitive skills
- Prenatal infection and neurodevelopmental disabilities
- Gene–environment interactions and behavior
- Prenatal and perinatal infection and schizophrenia
- Family influences on child health and development
- Impact of neighborhood and communities on child health
- Impact of media exposure on child health and development
- Social institutions and child health and development
- Influences on healthy development
- The role of prenatal maternal stress and genetics in childhood asthma
- Exposure to indoor and outdoor air pollution, aeroallergens, and asthma risk
- Dietary antioxidants and asthma risk
- Social environmental influences on asthma disparities
- Early exposure to structural components and products of microorganisms decreases the risk of asthma
- Environmental exposures interact with genes to increase the risk of asthma and wheezing in children
- Obesity and insulin resistance from impaired maternal glucose metabolism
- Obesity and insulin resistance from intrauterine growth restriction
- Breastfeeding associated with lower rates of obesity and lower risk of insulin resistance
- Fiber, whole grains, high glycemic index and obesity and insulin resistance
- Genetics, environmental exposures, and type 1 diabetes
- Repeated mild traumatic brain injury and neurocognitive development
- Behavioral exposures, genetics, and childhood or adolescence onset aggression
- Antecedents and resiliency to traumatic life events in childhood
- Hormonally active environmental agents and reproductive development

Source: NCS Research Plan, Version 1.3

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# Appendix C.3

# Summary of Data Collection Activities

# NCS PROTOCOL OVERVIEW AND SUMMARY OF CONTACTS
## November 28, 2007

| | Pre- Pregnancy | | | | | Pregnancy | | | | | | | | | Birth | | | | Post-natal | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | P1 Home | Within X days of P1[1] | P 1 Month (Phone) | P 2 Month (Phone) | P 4 Month (Phone) | T1-1st (Home) | T1 - Prior (Home) | Within X Days of T1[1] | 16-17 Weeks (Phone) | T2 (Clinic) | T3-Prior (Clinic) | T3-1st (Home)[2] | Within X days of T3[1] | 36 Weeks (Phone) | B1 Delivery (Hospital) | B2 Pre-discharge (Hospital) | Within X weeks of B2[1] | 1 month visit if needed[3] (Home) | 3 Months (Phone) | 6 Month Visit (Home) | Within X days of 6 Mo. Visit[1] | 9 Months (Phone) | 12 Month Visit (Home) | Within X days of 12 Mo. Visit[1] | 18 Mos. (Phone) | 24 Mos. (Phone) |
| **Informed Consent/Detailed Visit Information/Medical Release as Needed** | M | | | | | M F | M F | | | | | M | | | M | M | | M | | M | | | M F | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Interviews/Assessments/Questionnaires** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| In-Person/Phone | M | | M | M | M | M F | M F | | M | | M | M | | M | | | | | M | M C | | M | M F C | | M | M |
| Self-Administered Questionnaire | | M | | | | | | M F | | | | | M | | | | M | | | | M F | F | | M F | F | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Diaries/Medical Visit Logs** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pregnancy Diary | | | | | | M | M | | | | | | | → | | | | | | | | | | | | |
| Medical Provider Visit Log | | | | | | M | M | | | | | | | → | | C | | | | | | | | | | → |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Environmental** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Indoor Air | M | | | | | M | M | | | | | M | | | | | | | | X | | | X | | | |
| House Dust | M | | | | | M | M | | | | | M | | | | | | | | X | | | X | | | |
| Drinking Water | M | | | | | M | M | | | | | M | | | | | | | | X | | | X | | | |
| Soil | | | | | | | | | | | | | | | | | | | | X | | | X | | | |
| Visual Assessment | M | | | | | M | M | | | | | M | | | | | | | | X | | | X | | | X |
| Indoor Air (self-collected) | | | | | | | | | | | | | M[4] | | | | | | | | | | | | | X |
| House Dust (self-collected) | | | | | | | | | | | | M | M[4] | | | | | | | | | | | | | X |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Physical Exam** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Anthropometric | M | | | | | M F | M F | | | | M | M | | | | C | | C | | C | | | C | | | |
| Blood Pressure | M | | | | | M F | M F | | | | M | M | | | | | | | | C | | | C | | | |
| Ultrasound | | | | | | | | M[5] | | M | M | | M[6] | | | | | | | | | | | | | |
| Dysmorphology | | | | | | | | | | | | | | | | C | | C | | | | | | | | |
| Physical Exam | | | | | | | | | | | | | | | | | | | | C | | | C | | | |
| Lung Function | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Observational Photos | | | | | | | | | | | | | | | | C | | C | | C | | | C | | | |
| Physical Activity | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hearing Assessment | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Vision Assessment | | | | | | | | | | | | | | | | | | | | | | | | | | |
| BIA | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Biospecimen Collection** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pregnancy Tests (self-collected) | | M | | | | | | | | | | | | | | | | | | | | | | | | |
| Vaginal Swabs | M | | | | | M | M | | | | M | M | | | | | | | | | | | | | | |
| Blood/Buccal Cell[7] | M | | | | | M F | M F | | | | M | M | | | M | | | | | | | | C | | | |
| Blood Spot (heel and cord) | | | | | | | | | | | | | | | C | | | | | | | | | | | |
| Urine (self-collected) | M | M[8] | | | | M F | M F | | | | M | M | | | | | | | | C | | | C | | | |
| Hair | M | | | | | M F | M F | | | | M | M | | | | | | | | | | | C | | | |
| Nails | | | | | | F | F | | | | M | M | | | | | | | | | | | | | | |
| Cord Blood | | | | | | | | | | | | | | | C | | | | | | | | | | | |
| Umbilical Cord | | | | | | | | | | | | | | | M | | | | | | | | | | | |
| Placenta | | | | | | | | | | | | | | | M | | | | | | | | | | | |
| Meconium | | | | | | | | | | | | | | | | C | | | | | | | | | | |
| Breast Milk (self-collected) | | | | | | | | | | | | | | | | | | M | M | M | | | | | | |
| Saliva (self-collected) | | | | | | | | M | | | M | M | | | | | | | | | M F | | | C | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Other** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Medical Record/Chart Abstraction | | | | | | | | M[5] | | | | | | | | M C | | | | | | | | | | |
| Community Based Food, Air, and Water Collection | | | | | | | | M[9] | → | → | → | → | → | → | | | → | → | X[9] | → | → | → | → | → | → | → |
| Child Care Locations | | | | | | | | | | | | | | | | | | | | | | CC | | | | CC |
| Neighborhood Assessment | | | | | | | | M[9] | → | → | → | → | → | → | | | → | → | X[9] | → | → | → | → | → | → | → |

**KEY: M=MOTHER F=FATHER C=CHILD X=CHILD'S PLACE OF RESIDENCE CC=CHILD'S CHILD CARE LOCATION(S)**

[1] Activity is initiated at in-person visit and requires participant action after the visit (e.g., mail in self-collected urine sample, complete self-administered questionnaire and mail in). Time frame for completion varies and is specific to each activity.

[2] If a participant enrolls at 28 weeks or later, she will have a modified T3 visit in the home that includes obtaining some baseline measures from T1 visit as well as additional T3 protocol activities.

[3] A home visit will be conducted at 1 month if certain child measures are not completed at the birth visit.

[4] Self-collected environmental samples will not be collected if the T3 visit is the participant's first visit.

[5] This ultrasound will only be conducted for women who do not already have a 1st trimester ultrasound as part of routine care (see protocol).

[6] If the participant's first visit is the T3 visit, the T3 ultrasound will be done at a clinic, separate from the T3 home visit.

[7] Buccal cells for DNA will be collected as a backup from the mother and father at the T1 First or Prior visit and the child at the 36 month visit when blood is not drawn.

[8] These biospecimen collections are intended to measure environmental exposures closer to the time of conception and includes two separate collections.

[9] Community samples and assessments will be collected at regular intervals throughout this time period. The collections/assessments are not connected to a specific visit.

# NCS PROTOCOL OVERVIEW
## SUMMARY OF QUESTIONNAIRE AND PSYCHOLOGICAL/DEVELOPMENTAL ASSESSMENTS
## January 21, 2008



| | Pre-Pregnancy | | | | | Pregnancy | | | | | | | | | Birth | | | | Post-Natal | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | P1 Home | Within X Days of P1[1] | P 1 Month (Phone) | P 2 Month (Phone) | P 4 Month (Phone) | T1 - 1st[2] (Home) | T1 - Prior[2] (Home) | Within X Days of T1[1] | 16-17 Weeks (Phone) | T2 (Clinic) | T3 - Prior (Clinic) | T3 - 1st (Home)[3] | Within X Days of T3[1] | 36 Weeks (Phone) | B1 Delivery (Hospital) | B2 Pre-discharge (Hospital) | Within X Weeks of B2[1] | 1-Month Visit if Needed[4] (Home) | 3 Months (Phone) | 6-Month Visit (Home) | Within X Days of 6-Mo. Visit[1] | 9 Months (Phone) | 12-Month Visit (Home) | Within X Days of 12-Mo. Visit[1] | 18 Mos. (Phone) | 24 Mos. (Phone) |
| Informed Consent /Detailed Visit Information/ Medical Release As Needed | M | | | | | M F | M F | | | | | M | | | M | | | M | | M F | | | M F | | | |
| Interview/Assessments | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Household Composition and Demographics** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Household Composition | M | | | | | M | | | | | | M | | | | | | | | M | | | | | | |
| Age, race, ethnicity, relationship, marital status | M | | | | | M F | F | | | | | M | | | | | | | | M | | | | | | |
| Education | M | | | | | M F | F | | | | | M | | | | | | | | | | | | | | |
| Income (acasi) | | | | | | M | M | | | | | M | | | | | | | | M | | | | | | |
| Supported by family income (acasi) | | | | | | M | M | | | | | M | | | | | | | | M | | | | | | |
| Food security | M | | | | | M F | F | | | | | M | | | | | | | | | | | M | | | |
| Health insurance | M | | | | | M F | F | | | | | M | | | | | | | | M | | | M | | | |
| Social status | M | | | | | M F | F | | | | | M | | | | | | | | | | | | | | |
| Religious affiliation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Culture and acculturation | M | | | | | M F | F | | | | | M | | | | | | | | M | F | | | | | |
| **Contact and Tracing** | M | | | | | M | | | | | | | | | | | | | | M | | | | | | |
| **Perceived Stress** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Global Perceived Stress | | | | | | M | M | | | | M | M | | | | | | | | M | | | | | | |
| Racism/Discrimination | | | | | | M | M | | | | | | | | | | | | | | | | | | | |
| Life Events (self-administered) | | | | | | | | | | | M | M | | | | | | | | | | | | | | |
| Parenting Stress | | | | | | | | | | | | | | | | | | | | | M | | | | | |
| Work/Family Stress | | | | | | | | | | | | | | | | | | | | | | | | M | | |
| **Social Support** | | | | | | M | M | | | | M | M | | | | | | | | M | | | | | | |
| **Family Process** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Quality of Relationships | | | | | | | | | M | | | | | | | | | | | | F | M | | M F | F[5] | |
| Domestic Violence (acasi) | | | | | | M | M | | | | M | M | | | | | | | | | | | | M | | |
| Division of Labor | | | | | | | | | | | | | | | | | | | | | M | F[5] | | | | |
| **Health Behaviors (maternal)** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Physical Activity | M | | | | | M | M | | | | | | | | | | | | | | | | | | | |
| Maternal Sleep | M | | | | | M | M | | | | | | | | | | | | | M | | | | | | |
| Douching (acasi) | | | | | | M | M | | | | | | | | | | | | | | | | | | | |
| Caffeine Use | M | | | | | M | M | | | | | | | | | | | | | | | | | | | |
| Tobacco Use (acasi) | | | | | | M | M | | | | M | M | | | | | | | | | | | | | F[5] | |
| Environmental Tobacco Smoke Exposure (acasi) | | | | | | M | M | | | | | | | | | | | | | M | F | | M | F | | |
| Alcohol Use (acasi) | | | | | | M | M | | | | M | M | | | | | | | | | | | | | F[5] | |
| Binge Drinking (acasi) | | | | | | M | M | | | | M | M | | | | | | | | M | | | M | | | |
| Illicit Drug Use and Abuse of Prescription Drugs (acasi) | | | | | | M | M | | | | | | | | | | | | | | | | | | | |
| **Diet and Toxicant Exposure through Food (mother)** | | | | M | | | | | | | | | | | | | | | | | | | | | | |
| - Food Frequency Questionnaire (self-administered questionnaire) | | M | | | | | | M | | | | | M | | | | M | | | | | | | | | |
| - 3-Day Checklist (self-administered questionnaire) | | M | | | | | | M | | | | | M | | | | | | | | | | | | | |
| **Diet and Toxicant Exposures through Food (child)** | | | | | | | | | | | | | | | | | | | M | | | | | | | |
| - Child Feeding Form (mailed self-administered questionnaire) | | | | | | | | | | | | | | | | | M | | | | M | | | M | | |
| - Child FFQ (mailed self-administered questionnaire) | | | | | | | | | | | | | | | | | | | | | | | | | M[5] | |
| - Child 3-day Checklist (mailed self-administered questionnaire) | | | | | | | | | | | | | | | | | | | | | M | | | M | M[5] | |
| **Mental Health & Cognition** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Depression | | | | | | M | M | | | | M | M | | | | | | | | M | F | | | | | |
| State Trait Anxiety | | | | | | | | | | | | | | | | | | | | | M | | | | | |
| IQ | | | | | | F | F | | | | | | | | | | | | | | | | F | | | |
| Literacy | | | | | | | | | | | | | | | | | | | | M | | | F | | | |
| Mental Health (CIDI Screener) | | | | | | F | F | | | | | | | | | | | | | | | | | | | |
| **Maternal / Paternal Attachment** | | | | | | | | | | | | | | | | | | | | | | F[5] | | | M | |



***DRAFT***

# NCS PROTOCOL OVERVIEW
## SUMMARY OF QUESTIONNAIRE AND PSYCHOLOGICAL/DEVELOPMENTAL ASSESSMENTS
## January 21, 2008



| | Pre-Pregnancy | | | | | Pregnancy | | | | | | | | | Birth | | | | Post-Natal | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | P1 Home | Within X Days of P1[1] | P 1 Month (Phone) | P 2 Month (Phone) | P 4 Month (Phone) | T1 - 1st[2] (Home) | T1 - Prior[2] (Home) | Within X Days of T1[1] | 16-17 Weeks (Phone) | T2 (Clinic) | T3 - Prior (Clinic) | T3 - 1st (Home)[3] | Within X Days of T3[1] | 36 Weeks (Phone) | B1 Delivery (Hospital) | B2 Pre-discharge (Hospital) | Within X Weeks of B2[1] | 1-Month Visit if Needed[4] (Home) | 3 Months (Phone) | 6-Month Visit (Home) | Within X Days of 6-Mo. Visit[1] | 9 Months (Phone) | 12-Month Visit (Home) | Within X Days of 12-Mo. Visit[1] | 18 Mos. (Phone) | 24 Mos. (Phone) |
| **Child Care** | | | | | | | | | | | | | | | | | | | M | M | | M | M | | M | M |
| **Neighborhood** | | | | | | | | | | | | | | | | | | | | | | | | | M | |
| **Financial Security and Program Participation** | | | | | | | | | | | M | M | | | | | | | | M | | | M | | | |
| **Housing Characteristics/In home exposures** | | | | | | M | M | | | | M | M | | | | | | | | M | | | M | | M | |
| **Occupational/Hobby Exposures** | M | | | | | M F | M F | | | | M | M | | | | | | | | | | | | | F[5] | |
| **Take Home (Occupational) Exposures** | | | | | | | | | | | | | | | | | | | | M | F | | M | F | M | |
| **Commuting** | | | | | | M | M | | | | | | | | | | | | | | | | | | | |
| **Product Use Questionnaire** | | | | | | M | M | | | | M | M | | | | | | | | M | | | M | | | M |
| **Pets and Pesticide Use** | M | | | | | M | M | | | | M | M | | | | | | | | M | | | M | | M | M |
| **Use of Medicines (mother)** | M | | | | | M | M | | | | M | M | | | | | | | | | | | | | | |
| **Use of Medicines (child)** | | | | | | | | | | | | | | | | | | | | M | | | M | | M | M |
| **Time and Activity (mother) (self-administered questionnaire)** | | | | | | | | M | | | | | M | | | | | | | | | | | | | |
| **Time and Activity (child)** | | | | | | | | | | | | | | | | | | | | | M | | | M | | M[5] |
| **Medical History (maternal/paternal)** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Current Pregnancy Information | | | | | | M | M | | M | | M | M | | M | | | | | | | | | | | | |
| Use of Fertility Services | | | | | | M | M | | | | | M | | | | | | | | | | | | | | |
| Biological Father Information | | | | | | M | M | | | | | M | | | | | | | | | | | | | | |
| Prenatal Care, Doctor Visits, Hospitalizations | | | | | | M | M | | M | | M | M | | M | | | | | | | | | | | | |
| Birth History | | | | | | M | M | | | | | M | | | | | | | | | | | | | | |
| Pregnancy and Reproductive History (acasi) | | | | | | M | M | | | | | M | | | | | | | | | | | | | | |
| Medical History and Conditions | | | | | | M F | M F | | | | | M | | | | | | | | | | | | | | |
| Dental Health | | | | | | M | M | | | | | M | | | | | | | | | | | | | | |
| Health Status/Functional Limitations/Impairment | | | | | | M | M | | | | | | | | | | | | | | | | | | | |
| Family Medical History (self-administered questionnaire) | | | | | | | | F | | | | | | | | | | | | | M | | | | | |
| **Medical History (child)** | | | | | | | | | | | | | | | | | | | M | M | | M | M | | M | M |
| Persistent crying/Colic | | | | | | | | | | | | | | | | | | | M | | | | | | | |
| Developmental milestones | | | | | | | | | | | | | | | | | | | M | M | | M | M | | M | M |
| **Parenting Practices/Behaviors and Media Exposure** | | | | | | | | | | | | | | | | | | | | M | F | F[5] | M | F | F[5] | M |
| **Major life events** | | | | | | | | | | | | | | | | | | | | | | | | | M | M |
| **Future Plans for Child (feeding, sleeping, living arrangements)** | | | | | | | | | | | M | M | | | | | | | | | | | | | | |
| **Child Language Development** | | | | | | | | | | | | | | | | | | | | | | | M | | | |
| **Child Temperament / Emotional Regulation** | | | | | | | | | | | | | | | | | | | | | M | | | | M | |
| **Child Socio-Emotional Functioning / Behavior** | | | | | | | | | | | | | | | | | | | | | | | | | | M |
| **Child Social Competence** | | | | | | | | | | | | | | | | | | | | | | | | M | | |
| **Child Autism Screening** | | | | | | | | | | | | | | | | | | | | | | | | | | M |
| **Child Adaptive Behavior** | | | | | | | | | | | | | | | | | | | | | | | | | | M |
| **Neurobehavioral Assessments** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Neonatal Neurobehavior | | | | | | | | | | | | | | | | C | | C | | | | | | | | |
| General Cognitive Ability | | | | | | | | | | | | | | | | | | | | | | | M C | | | |
| General Motor Development | | | | | | | | | | | | | | | | | | | | | | | C | | | |
| Language Development | | | | | | | | | | | | | | | | | | | | | | | C | | | |
| Parent-Child Interaction | | | | | | | | | | | | | | | | | | | | M C | | | C F | | | |

**KEY: M=MOTHER F=FATHER C=CHILD**

[1] Activity is initiated at in-person visit and requires participant action after the visit (e.g., mail in self-collected urine sample, complete self-administered questionnaire and mail in). Time frame for completion varies and is specific to each activity.

[2] T1 Prior measures and activities will be conducted with the respondents who were enrolled prior to conception and completed a P1 visit. The T1 First visit will be conducted with women who are enrolled during their 1st trimester of pregnancy.

[3] If a participant enrolls at 28 weeks or later, she will have a modified T3 visit in the home that includes obtaining some baseline measures from T1 visit as well as additional T3 protocol activities.

[4] This visit is only conducted if certain child measures are not completed at the B2 (pre-discharge) visit.

[5] A self-administered questionnaires will be mailed to the respondent to complete. These topics will not be included in the phone interview.



*DRAFT*

# NCS Biospecimen Collections--January 2008



| | Pre- Pregnancy | | Pregnancy | | | | | Birth | | | Post-natal | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Specimen Type (amount collected)** | **P1 Home** | **Within X Days of P1** | **T1 - 1st (Home)** | **T1 - Prior (Home)** | **Within X Days of T1** | **T3 (Clinic or Home)** | **Within X Days of T3** | **B1 Delivery (Hospital)** | **B2 Pre-discharge (Hospital)** | **1 Month Visit if Needed (Home)** | **3 Months (Phone)** | **6-Month Visit (Home)** | **Within X Days of 6-Mo. Visit** | **12-Month Visit (Home)** | **Within X Days of 12-Mo. Visit** |
| **Maternal** | | | | | | | | | | | | | | | |
| Blood | 43 mL (5 tubes) | | 53 mL (6 tubes) | 53 mL (6 tubes) | | 67 mL (8 tubes) | | 33 mL (4 tubes) | | | | | | | |
| Spot Urine | 40 mL | | 40 | 40 | | 40 | | | | | | | | | |
| Pregnancy Urine (mL) **P1 study participants will be asked to collect a urine sample the morning after their positive pregnancy test. | | | | 40 | | | | | | | | | | | |
| Vaginal Swabs (3 swabs) | X | | X | X | | X | | | | | | | | | |
| Hair (~20 strands) | X | | X | X | | X | | | | | | | | | |
| Nails (clippings from all teos) | | | | | | X | | | | | | | | | |
| Saliva (3 collections per day for 2 days) | | | | | X | X | | | | | | | X | | |
| Cord Blood | | | | | | | | 68 mL (9 tubes) | | | | | | | |
| Placenta and Umbilical Cord (size measurements, weight, photographs, tissue blocks, tissue samples) | | | | | | | | X | | | | | | | |
| Breast Milk (mL) ***A Breast Milk kit will be given at the birth visit and milk will be collected at 1 and 3 months and mailed in or picked up; At the 6 month visit a breast milk collection kit will be left with the mothers who are still nursing, and the breast milk will be picked up with the saliva after the visit. | | | | | | | | | | 80-100 mL | 80-100 mL | | 80-100 mL | | |
| | | | | | | | | | | | | | | | |
| **Paternal** | | | | | | | | | | | | | | | |
| Blood | | | 33 mL (4 tubes) | 33 mL (4 tubes) | | | | | | | | | | | |
| Urine | | | 40 | 40 | | | | | | | | | | | |
| Hair (~20 strands) | | | X | X | | | | | | | | | | | |
| Nails (clippings from all teos) | | | X | X | | | | | | | | | | | |
| Saliva (3 collections per day for 2 days) | | | | | | | | | | | | | X | | |
| | | | | | | | | | | | | | | | |
| **Child** | | | | | | | | | | | | | | | |
| Heel Stick (5 spots per Guthrie Card) | | | | | | | | | X | | | | | | |
| Meconium (at least one sample from each child) | | | | | | | | | X | | | | | | |
| Blood | | | | | | | | | | | | | | 19 mL (4 tubes) | |
| Urine (amount from diaper will vary) | | | | | | | | | | | | X | | X | |
| Hair (~20 strands) | | | | | | | | | | | | | | X | |
| Saliva (2 collections per day for 2 days) | | | | | | | | | | | | | | | X |
| | | | | | | | | | | | | | | | |

# Analytes in Biospecimen Collected for NCS--January 2008



| Biospecimen | Immediate Analysis (performed on all samples collected) | Potential analytes to Address NCS Hypotheses (analysis to be included in future case-control studies) |
|---|---|---|
| Blood | Hemoglobin/calculated hematocrit | Stress hormones (e.g. cortisol, corticotropin releasing hormone, ACTH)<br>Reproductive hormones (e.g. estriol, estradiol, progesterone)<br>Infection and inflammation indicators (e.g. cytokines, interleukins, multiple Ig types)<br>Glucose metabolism analytes (e.g. fasting blood glucose levels, insulin levels, HgbA1C)<br>Nutritional analytes (e.g. RBC folate, vitamins, omega 3 fatty acids, )<br>Metals (e.g. mercury, lead, cadmium)<br>Non-persistent Pesticides (e.g. metabolites of atrazine, organophosphorus pesticides, and pyrethroid insecticides)<br>Environmental phenols (e.g. bisphenol A and parabens)<br>Persistent Organic Chemicals (e.g. dioxins and furans)<br>Genetic Material to be collected (genomic and mitochondrial DNA, RNA, Peripheral blood mononuclear cells (PBMCs) |
| Urine | Self-administered pregnancy test after pre-pregnancy visit | Creatinine<br>Illicit drug panel and cotinine<br>Phytoestrogens<br>Phthalates<br>Perchlorate and iodide<br>Stress hormone (cortisol)<br>Infection indicators (PCR for Chlamydia/Gonnorhea)<br>Metals (e.g. mercury, arsenic)<br>Environmental phenols (e.g. bisphenol A)<br>Non-persistent Pesticides (e.g. metabolites of atrazine, organophosphorus pesticides, and pyrethroid insecticides) |
| Vaginal Swabs | pH at 3rd trimester clinic visit | Infection and inflammation indicators (bacterial vaginosis, antibodies, cytokines, metalloproteinase) |
| Hair | None | Cotinine<br>Total mercury |
| Nails | None | Metals (e.g. mercury, arsenic) |
| Saliva | None | Stress hormone (cortisol) |
| Placenta and Umbilical Cord | Size measurements, weight and photographs | Infection and inflammation indicators (e.g. cytokines, antibodies)<br>Chemical contaminants (to be determined) |
| Cord Blood | Hemoglobin/calculated hematocrit | Stress hormones (e.g. cortisol, corticotropin releasing hormone, ACTH)<br>Reproductive hormones (e.g. estriol, estradiol, progesterone)<br>Infection and inflammation indicators (e.g. cytokines, interleukins, multiple Ig types)<br>Glucose metabolism analytes (e.g. fasting blood glucose levels, insulin levels, HgbA1C)<br>Nutritional analytes (e.g. RBC folate, vitamins, omega 3 fatty acids, )<br>Metals (e.g. mercury, arsenic)<br>Non-persistent Pesticides (e.g. metabolites of atrazine, organophosphorus pesticides, and pyrethroid insecticides)<br>Environmental phenols (e.g. bisphenol A and parabens)<br>Persistent Organic Chemicals (e.g. dioxins and furans)<br>Genetic Material to be collected (genomic and mitochondrial DNA, RNA, Peripheral blood mononuclear cells (PBMCs) |
| Meconium | None | Cotinine<br>Organophosphate metabolites |
| Breast Milk | None | Nutritional analytes (e.g. antioxidants, lipids, carbohydrates, endogenous compounds )<br>Phytoestrogens and other hormones<br>Perchlorate, iodide, thiocynate, nitrate<br>Metals (maganese and others)<br>Non-persistent Pesticides (e.g. metabolites of atrazine, organophosphorus pesticides, and pyrethroid insecticides)<br>Environmental phenols (e.g. bisphenol A and parabens)<br>Persistent Organic Chemicals (e.g. dioxins and furans) |

## NCS PROTOCOL SUMMARY OF ENVIRONMENTAL SAMPLES BY CONTACT (FOR THE SAME HOME)
## DRAFT -- 9/19/2007

| | | | Pre- Pregnancy | | Pregnancy | | | | | Birth | Post-natal | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | P1 Home | Within X days of P1 | T1 - 1st (Home) | T1 - Prior (Home) | Within X Days of T1 | T3 (Clinic) | Within X Days of T3 | Birth Visit (Hospital) | 6 Month Visit (Home) | 12 Month Visit (Home) | 24 Months (Phone) |
| **Indoor Air** | **Method** | **% Homes** | | | | | | | | | | | |
| PM2.5 - metals (XRF); total carbon (reflectance) (filter to be archived after weighing)[1] | Pump | 100 | X | PU | X | X | PU | | | | X, PU | X, PU | |
| VOCs (Note: 10% subsample in pilot) | Badge | 10 (pilot) | X | PU | X | X | PU | | | | X, PU | X, PU | |
| Carbonyls (Aldehydes & Ketones) | Badge | 100 | | | X | X | | X[5] | Return | | X, PU | X, PU | X[5], return |
| $NO_2$ (Trigger: unvented flame source, e.g., cookstove, space heater, present, plus 2-3% without source) | Badge | 50 | | | X | X | PU | X[5] | Return | | X, PU | X, PU | X[5], return |
| $O_3$ (Trigger: source, e.g., electrostatic filter, ozonator, laser printer present, plus 5% without source) | Badge | 25 | | | | | | | | | X, PU | X, PU | |
| **House Dust** | | | | | | | | | | | | | |
| Allergens, endotoxin (to be archived) | Vacuum | 100 | | | X | X | | | | | X | X | X[5], return |
| Mold (to be archived) | Vacuum | 100 | | | | | | | | | X | X | |
| Inorganics/metals (wipe to be archived) | Wipe | 100 | | | X | X | | | | | X | | |
| Deposition plate (method TBD, to be archived) | Plate | 100 | | | | | | X[3,5] | Return after birth | | | | |
| SVOCs (wipe to be archived) | Wipe | 100 | | | X | X | | | | | X | | |
| Pesticides: Pyrethroids (composite, store P1 wipes for 3 mos to determine pregnancy) | Wipe | 100 | X | | X | X | | | | | X | X | X[5], return |
| **Drinking Water [5]** | | | | | | | | | | | | | |
| Disinfection Byproducts (DBPs) - HAA9, THMs | Water | 1+ per segment/ system/ year | | | C | C | | | | | | C | C |
| VOCs (pilot) | Water | 12 (pilot) [2] | | | X | X | | | | | X | X | |
| **Soil** | | | | | | | | | | | | | |
| Composited play area soil (to be archived) | Soil | 100 (1 per structure) | | | | | | | | | X | X | |
| **Visual Assessment - Indoor, outdoor[4]** | | | X | | X | X | | | | | X | X | X |

**Notes:**

X = Sample will be collected at contact. PU = Pick up sample (Pump and badge samples will be left in place for 6-7 days). C = Community sample.

[1] May also do PM2.5 or PM2.5-10 if suitable indoor methods are identified.

[2] Where private wells provide tap water.

[3] Deploy plate at T3 contact (self collection) and mail back at 1-month.

[4] Some observational data will be gathered by neighborhood drive arounds / extant data sources.

[5] Self-collected samples - Activity is initiated at in-person visit or is mailed to the participant and requires participant action (e.g., collect and mail in badge). Time frame for completion varies and is specific to each activity.

### Community Outdoor Air - 9/17/07

Note: Each SC will likely be asked to submit a proposal for community outdoor air sampling, based on<u>e</u> of the three options listed under this table. The NCS PO is still deciding how best to handle outdoor sampling. The focus will be on supplementing existing ambient air monitoring data (if not near enough to the segment). Implementation will depend on costs and how SC plans to utilize the data in air and/or exposure modeling efforts.

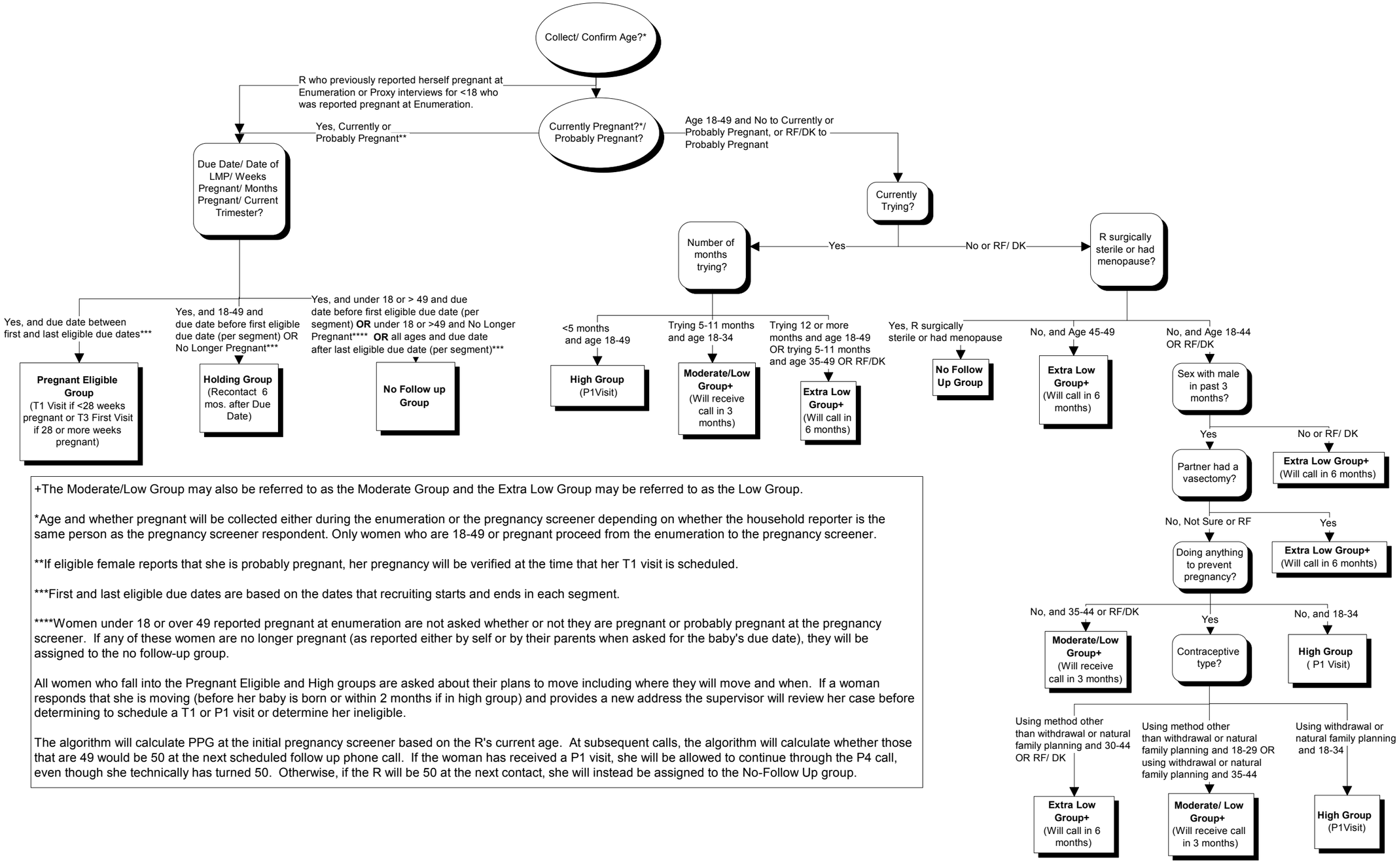
| |
|---|
| $PM_{2.5}$ - Metals (XRF), total carbon (reflectance) (filter to be archived after weighing) |
| $PM_{10}$ (filter to be archived after weighing) |
| $NO_2$, NOx |
| $SO_2$ |
| $O_3$ |

Options for supplemental community outdoor monitoring (SC will propose one, based on their communities and propsed modeling):
1) One set of sampling equipment (same as that used for indoor air) to be rotated among segments on a quarterly basis for ~1 week periods.
2) One ambient air monitoring station placed in PSU - hourly, continuos measures. This assumes that the equipment will be provided by NCS; placement, operation, maintenance, and calibration provided by the Study Center (will need to identify qualified staff).
3) For LUR or other modeling - up to 3 $NO_2/NO_x$ Ogawa badges taken in each segment simultaneously 2x/year (~2 weeks each), or one PM2.5 (and/or PM10) sampler in each segment (could be simultaneous or rotating)

| Contact Schedule Physcial Measures 1-16-08 | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pre- Pregnancy | | | | | Pregnancy | | | | | | | | Birth | | | | Post-Natal | | | | | | | |
| Physical Measures | P1 Home | Within X Days of P1[1] | P 1 Month (Phone) | P 2 Month (Phone) | P 4 Month (Phone) | T1 - 1st (Home) | T1 - Prior (Home) | Within X Days of T1[1] | 16 - 17 Weeks (Phone) | T2 | T3 (Clinic) | Within X Days of T2/T3[1] | 36 Weeks (Phone) | B1 Delivery (Hospital) | B2 Pre-discharge (Hospital) | Within X weeks of B2[1] | 1 Month Visit if Needed[2] (Home) | 3 Months (Phone) | 6 Month Visit (Home) | Within X Days of 6 Mo. Visit[1] | 9 Months (Phone) | 12 Month Visit (Home) | Within X Days of 12 Mo. Visit[1] | 18 Mos. (Phone) | 24 Mos. (Phone) |
| **Anthropometric Measures** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Weight (2 measures) | X | | | | | X | X | | | | X | | | | | | | | | | | | | | |
| Maternal Standing Height (2) | X | | | | | X | | | | | | | | | | | | | | | | | | | |
| Maternal Sitting Height (2 | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Maternal Mid Arm Circumference (2) | X | | | | | X | X | | | | X | | | | | | | | | | | | | | |
| Maternal Hip Circumference (2) | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Waist Circumference (2) | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Head Circumference (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Maternal Triceps Fold (2) | X | | | | | X | X | | | | X | | | | | | | | | | | | | | |
| Maternal Subscapular Skin Fold (2 | X | | | | | X | X | | | | X | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Weight (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Paternal Standing Height (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Paternal Sitting Height (2 | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Paternal Mid Arm Circumference (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Paternal Hip Circumference (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Paternal Waist Circumference (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Paternal Head Circumfereence (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Paternal Triceps Fold (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Paternal Subscapular Skin Fold (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infant Recumbant Length (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | |
| Child Height (2) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infant/Child Weight (2) | | | | | | | | | | | | | | | | | | | X | | | X | | | |
| Infant/Child Head Circumference (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | |
| Infant/Child Mid Upper Arm Circumference (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | |
| Infant/Child Abdomen Circumference (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | |
| Infant/Child Thigh Circumference (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | |
| Infant/Child Triceps Skin Fold (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | |
| Infant/Child Subscapular Skin Fold (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | |
| **Blood Pressure** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Blood Pressure | X | | | | | X | X | | | | X | | | | | | | | | | | | | | |
| Paternal Blood Pressure | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Infant/Child Blood Pressure | | | | | | | | | | | | | | | | | | | | | | X | | | |
| **Maternal/Fetal Ultrasound** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Crown rump length | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Gestational age | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Cardiac activity | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Presentation | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Biparietal Diameter (BPD) | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Head circumference (HC) | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Abdominal circumference (AC) | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Leg measured: (for FL, MTC, MTLC, MTA, MTLMA) | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| . Femur length (FL) | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Mid thigh circumference (MTC) | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Mid thigh lean mass circumference (MTLMC) | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Mid thigh total area (MTA) (calculated | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Mid thigh lean mass area (MTLMA | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Abdominal wall thickness (AWT) | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Gender | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| For Multiple Fetuses (in addition to above measures) | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Chorionicity | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Amnionicity | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Position of each fetus | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Estimated fetal weight | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Location of placenta | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| Membranes | | | | | | | | | | X | X | | | | | | | | | | | | | | |
| **Infant Dysmorphology** | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2-D Images | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Face-frontal | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Face-profile (right) | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Face-profile (left) | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Anogenital Distnce Measures | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Anterior penis to anus (AGD1) | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Posterior base of penis to anus (AGD2) | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Posterior of scrotum/fourchette to anus (AGD3) | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Surveillance methodology (no participant burden) | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| **Chart Abstraction - Prenatal, Labor, & Delivery** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prenatal care | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Prenatal labs | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Ultrasound findings | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Complications | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Prenatal procedures | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Admission information | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Labor information | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Delivery information | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Analgesia received in labor | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Medications | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| **Chart Abstraction - Neonatal** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Delivery information | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Post delivery information | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Complication during hospitalizatior | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Major congenital malformations | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Medications during hospital stay | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Oxygen/asssisted ventilation | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Immunization | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Circumcision | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Screening Tests | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Transfer information | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Discahrge weight | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Discharge information | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| Expired | | | | | | | | | | | | | | | X | | X | | | | | | | | |
| **Infant Physical Exam** | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2-D Images (for atopic dermatitis/eczema) | | | | | | | | | | | | | | | | | | | X | | | X | | | |
| Face-frontal | | | | | | | | | | | | | | | | | | | X | | | X | | | |
| Face-profile (right) | | | | | | | | | | | | | | | | | | | X | | | X | | | |
| Face-profile (left) | | | | | | | | | | | | | | | | | | | X | | | X | | | |
| Both hands (dorsal view) | | | | | | | | | | | | | | | | | | | X | | | X | | | |
| Both ears | | | | | | | | | | | | | | | | | | | X | | | X | | | |
| Both knees (popliteal fossa | | | | | | | | | | | | | | | | | | | X | | | X | | | |
| Both feet (dorsal view) | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |

| Contact Schedule Physcial Measures 1-16-08 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pre- Pregnancy | | | | | Pregnancy | | | | | | | | Birth | | | | Post-Natal | | | | | | | | | | | |
| Physical Measures | P1 Home | Within X days of P1[1] | P 1 Month (Phone) | P 2 Month (Phone) | P 4 Month (Phone) | T1-1st (Home) | T1 - Prior (Home) | Within X Days of T1[1] | 16-17 Weeks (Phone) | T2 | T3 (Clinic) | Within X days of T2/T3[1] | 36 Weeks (Phone) | B1 Delivery (Hospital) | B2 Pre-discharge (Hospital) | Within X weeks of B2[1] | 1 month visit if needed[2] (Home) | 3 Months (Phone) | 6 Month Visit (Home) | Within X days of 6 Mo. Visit[1] | 9 Months (Phone) | 12 Month Visit (Home) | Within X days of 12 Mo. Visit[1] | 18 Mos. (Phone) | 24 Mos. (Phone) | 30 Mos. (Phone) | 36 Month Visit (Clinic) | Within X days of 36 Month Visit[1] |
| **Anthropometric Measures** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Weight (2 measures) | X | | | | | X | X | | | | X | | | | | | | | | | | | | | | | | | |
| Maternal Standing Height (2) | X | | | | | X | | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Sitting Height (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Mid Arm Circumference (2) | X | | | | | X | X | | | | X | | | | | | | | | | | | | | | | | | |
| Maternal Hip Circumference (2) | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Waist Circumference (2) | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Head Circumference (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Triceps Fold (2) | X | | | | | X | X | | | | X | | | | | | | | | | | | | | | | | | |
| Maternal Subscapular Skin Fold (2) | X | | | | | X | X | | | | X | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Weight (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Standing Height (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Sitting Height (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Mid Arm Circumference (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Hip Circumference (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Waist Circumference (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Head Circumfereence (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Triceps Fold (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Paternal Subscapular Skin Fold (2) | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infant Recumbant Length (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | | | X | | |
| Child Height (2) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infant/Child Weight (2) | | | | | | | | | | | | | | | | | | | X | | | X | | | | | X | | |
| Infant/Child Head Circumference (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | | | X | | |
| Infant/Child Mid Upper Arm Circumference (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | | | X | | |
| Infant/Child Abdomen Circumference (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | | | X | | |
| Infant/Child Triceps Skin Fold (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | | | X | | |
| Infant/Child Subscapular Skin Fold (2) | | | | | | | | | | | | | | | X | | X | | X | | | X | | | | | X | | |
| **Blood Pressure** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Maternal Blood Pressure | X | | | | | X | X | | | | X | | | | | | | | | | | | | | | | | | |
| Paternal Blood Pressure | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Infant/Child Blood Pressure | | | | | | | | | | | | | | | | | | | | | | X | | | | | X | | |
| **Maternal/Fetal Ultrasound** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Crown rump length | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Gestational age | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | |
| Cardiac activity | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Presentation | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Biparietal Diameter (BPD) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Head circumference (HC) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Abdominal circumference (AC) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Leg measured: (for FL, MTC, MTLC, MTA, MTLMA) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Femur length (FL) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Mid thigh circumference (MTC) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Mid thigh lean mass circumference (MTLMC) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Mid thigh total area (MTA) (calculated) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Mid thigh lean mass area (MTLMA) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Abdominal wall thickness (AWT) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Gender | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| For Multiple Fetuses (in addition to above measures) | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Chorionicity | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Amnionicity | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Position of each fetus | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Estimated fetal weight | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Location of placenta | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Membranes | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| **Infant Dysmorphology** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2-D Images | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Face-frontal | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Face-profile (right) | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Face-profile (left) | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Anogenital Distnce Measures | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Anterior penis to anus (AGD1) | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Posterior base of penis to anus (AGD2) | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Posterior of scrotum/fourchette to anus (AGD3) | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Surveillance methodology (no participant burden) | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| **Infant Physical Exam** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2-D Images (for atopic dermatitis/eczema) | | | | | | | | | | | | | | | | | | | X | | | X | | | | | X | | |
| Face-frontal | | | | | | | | | | | | | | | | | | | X | | | X | | | | | | | |
| Face-profile (right) | | | | | | | | | | | | | | | | | | | X | | | X | | | | | | | |
| Face-profile (left) | | | | | | | | | | | | | | | | | | | X | | | X | | | | | | | |
| Both hands (dorsal view) | | | | | | | | | | | | | | | | | | | X | | | X | | | | | | | |
| Both ears | | | | | | | | | | | | | | | | | | | X | | | X | | | | | | | |
| Both knees (popliteal fossa | | | | | | | | | | | | | | | | | | | X | | | X | | | | | | | |
| Both feet (dorsal view) | | | | | | | | | | | | | | | | | | | X | | | X | | | | | | | |
| **Chart abstraction - Prenatal, Labor & Delivery** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prenatal care | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Prenatal labs | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Ultrasound findings | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Complications | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Prenatal procedures | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Admission information | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Labor information | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Delivery information | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Analgesia received in labor | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Medications | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Chart abstraction - Neonatal** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Delivery information | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Post delivery information | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Compilcation during hospitalization | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Major congenital malformations | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Medications during hospital stay | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Oxygen/asssisted ventilation | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Immunization | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Circumcision | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Screening Tests | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Transfer information | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Discahrge weight | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Discharge information | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| Expired | | | | | | | | | | | | | | | X | | X | | | | | | | | | | | | |
| **Bioelectrical Impedance Analysis** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| BIA | | | | | | | | | | | | | | | | | | | | | | | | | | | | X | |
| **Hearing Assessment** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Audiometry | | | | | | | | | | | | | | | | | | | | | | | | | | | | X | |
| **Vision Assessment** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acuity | | | | | | | | | | | | | | | | | | | | | | | | | | | | X | |
| **Lung Function** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Measure of lung function | | | | | | | | | | | | | | | | | | | | | | | | | | | | X | |
| **DXA** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Under consideration (possible adjunct study) | | | | | | | | | | | | | | | | | | | | | | | | | | | | ?? | |
| **Bone Ultrasound** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Under consideration | | | | | | | | | | | | | | | | | | | | | | ?? | | | | | | | |
| **Physical Activity** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Accelerometer (under consideration) | | | | | | | | | | | | | | | | | | | | | | | | | | | | ?? | |
| Time-Activity Diary | | | | | | | | | | | | | | | | | | | | | | | | | | | | ?? | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

# Initial Pregnancy Screener Algorithm 1.10.08




+The Moderate/Low Group may also be referred to as the Moderate Group and the Extra Low Group may be referred to as the Low Group.

*Age and whether pregnant will be collected either during the enumeration or the pregnancy screener depending on whether the household reporter is the same person as the pregnancy screener respondent. Only women who are 18-49 or pregnant proceed from the enumeration to the pregnancy screener.

**If eligible female reports that she is probably pregnant, her pregnancy will be verified at the time that her T1 visit is scheduled.

***First and last eligible due dates are based on the dates that recruiting starts and ends in each segment.

****Women under 18 or over 49 reported pregnant at enumeration are not asked whether or not they are pregnant or probably pregnant at the pregnancy screener. If any of these women are no longer pregnant (as reported either by self or by their parents when asked for the baby's due date), they will be assigned to the no follow-up group.

All women who fall into the Pregnant Eligible and High groups are asked about their plans to move including where they will move and when. If a woman responds that she is moving (before her baby is born or within 2 months if in high group) and provides a new address the supervisor will review her case before determining to schedule a T1 or P1 visit or determine her ineligible.

The algorithm will calculate PPG at the initial pregnancy screener based on the R's current age. At subsequent calls, the algorithm will calculate whether those that are 49 would be 50 at the next scheduled follow up phone call. If the woman has received a P1 visit, she will be allowed to continue through the P4 call, even though she technically has turned 50. Otherwise, if the R will be 50 at the next contact, she will instead be assigned to the No-Follow Up group.

# Follow Up Algorithm: P1, P2 and P4 Month Calls - 1.10.08

**High Group 1 - Trying to Become Pregnant**
(Women trying to become pregnant, ages 18-49 and trying 4 or less months)

was reported pregnant at Enumeration

Intro to P1/P2/P4 Month: I'm calling today just to update some information we have for you.

Learned Pregnant?

Yes

Due date/ First day of last menstrual period/ Weeks pregnant?

Eligible Due Date

**Pregnant Eligible Group**
(T1 Visit if <28 weeks pregnant or T3 First Visit if 28 or more weeks pregnant)

Congratulations again on your pregnancy. Because you're pregnant, we'd like to set up a visit at your home to tell you about the next phase of this study.

Ineligible Due Date

**Holding Group**
(Recontact 6 mos. after Due Date)

Congratulations again on your pregnancy. While this study focuses on child health, at this time we are only enrolling women whose babies are due between (DATE 1) and (DATE 2).** However, if you become pregnant again, that baby may be eligible for the study later on. We'll check in with you a few months after your baby is born to see how you're doing and update your information.

No

Still Trying?

Yes, and trying 4 months or less (calculated from start of P1 Month call)

**High Group**
(Continue calls through P4 - then move to Moderate/Low Group)

Need More Pregnancy Test Kits?

We'll call you in a month or two to see if anything has changed. In the meantime, if you learn that you're pregnant, please [insert local procedures].

No, or Yes and trying more than 4 months (calculated from start of P1 Month call)

**Moderate/Low Group+**
(Call in 3 months)***

Yes, trying

Need More Pregnancy Test Kits?

We'll call you in a month or two to see if anything has changed. In the meantime, if you learn that you're pregnant, please [insert local procedures].

No, not trying

We understand that plans can change and that you're not trying to become pregnant right now. We'll call you in a month or two to check in with you and see if anything has changed.

**High Group 2 - No Contraception**
(Women not trying and not using contraception ages 18-34)

**High Group 3 - High Failure Rate Contraception**
(Women not trying and using contraception with high failure rate ages 18-34)

Intro to P1/P2/P4 Month: I'm calling today just to update some information we have for you. Last time we spoke, you weren't trying to become pregnant, but we know that plans to start a family can sometimes change.

Are you now trying to become pregnant?

Yes

Learned pregnant?

No

**High Group**
(Continue calls through P4 - then move to Moderate/Low Group)

Inform will mail pregnancy test kits

We'll call you in a month or two to see if anything has changed. In the meantime, if you learn that you're pregnant, please [insert local procedures].

Yes

Due date/ First day of last menstrual period/ Weeks pregnant?

Eligible Due Date

**Pregnant Eligible Group**
(T1 Visit)

Congratulations again on your pregnancy. Because you're pregnant, we'd like to set up a visit at your home to tell you about the next phase of this study.

Ineligible Due Date

**Holding Group**
(Recontact 6 mos. after Due Date)

Congratulations again on your pregnancy. While this study focuses on child health, at this time we are only enrolling women whose babies are due between (DATE 1) and (DATE 2).** However, if you become pregnant again, that baby may be eligible for the study later on. We'll check back with you a few months after your baby is born to see how you're doing and update your information.

Currently Pregnant

No

Doing anything to prevent pregnancy?

No, and 35-44

**Moderate/Low Group+**
(Will receive call in 3 months)***

We'll call you in a month or two to check in with you and see if anything has changed.

Yes

Contraceptive type?

Using method other than withdrawal and natural family planning and age 30-44

**Extra Low Group+**
(Will call in 6 months)

We'll call you in about six months to check in with you and update your information.

Using method other than withdrawal and natural family planning and age 18-29 OR using withdrawal or natural family planning and 35-44

**Moderate/ Low Group+**
(Will receive call in 3 months)***

We'll call you in a month or two to check in with you and see if anything has changed.

Using withdrawal or natural family planning and age 18-34

**High Group**
(Continue calls through P4 - then move to Moderate/Low Group)

We'll call you in a month or two to check in with you and see if anything has changed.

No, and 18-34

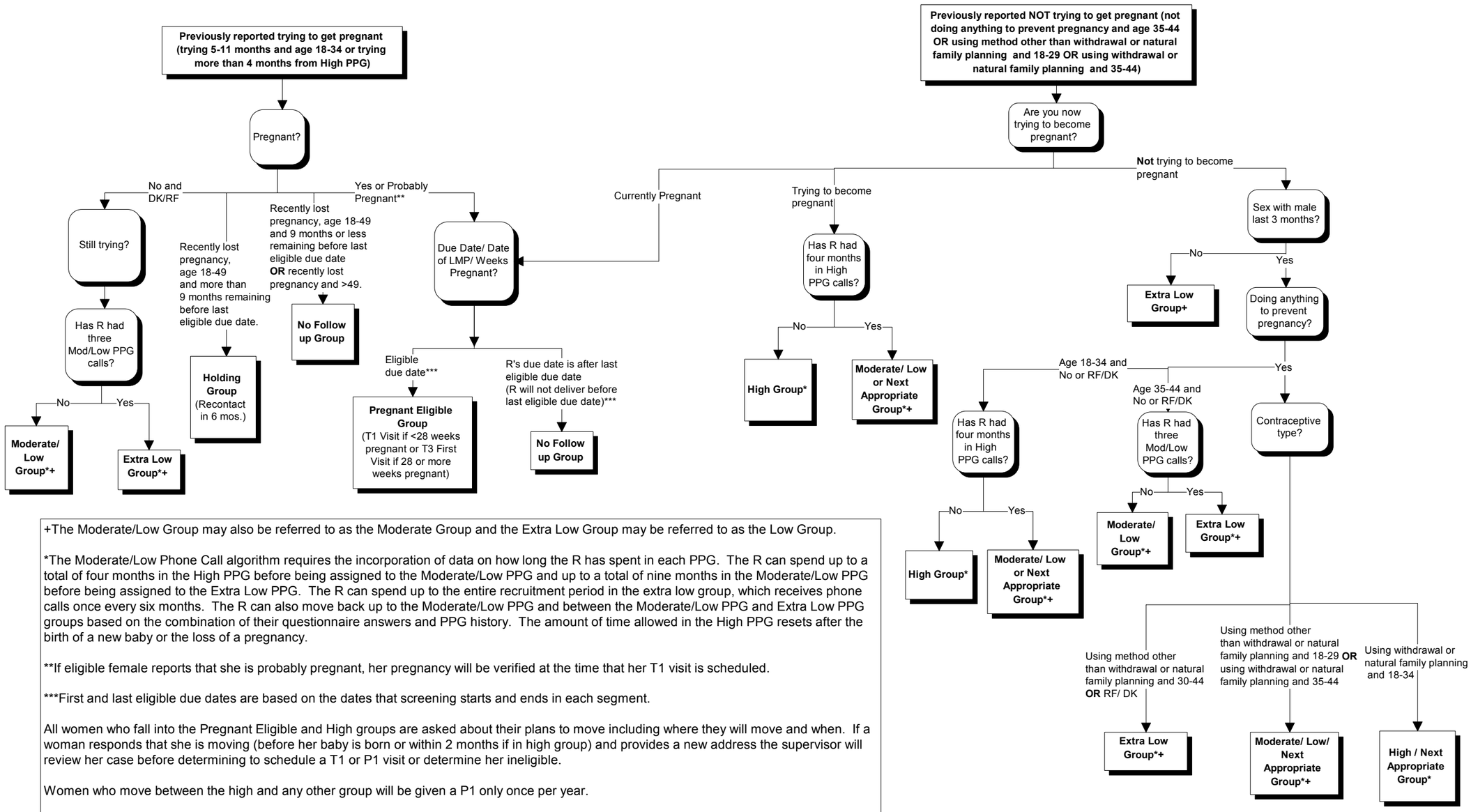
**High Group**
(Continue calls through P4 - then move to Moderate/Low Group)

We'll call you in a month or two to check in with you and see if anything has changed.

+The Moderate/Low Group may also be referred to as the Moderate Group and the Extra Low Group may be referred to as the Low Group.
*All women who fall into the Pregnant Eligible Group will be asked about their plans to move at the time the T1 visit is scheduled.
**(Date 1) and (Date 2) are the segment-specific first eligible due date and last eligible due date.
***The Moderate/Low Group will receive a total of 3 calls (1 every 3 months) before they are moved to the Extra Low Group.

The algorithm will calculate PPG based on the R's current age. For those that are 49, if they have had a P1 they will be allowed to continue through the P4 phone call, even if they have technically reached age 50. For those that would fall into the Moderate/Low, Extra Low or Holding Group, however,if the algorithm calculates the R would be 50 at the next scheduled follow up phone call, they will instead be assigned to the No Follow Up group.

# Moderate/Low Pregnancy Probability Group Call 1.10.08+




+The Moderate/Low Group may also be referred to as the Moderate Group and the Extra Low Group may be referred to as the Low Group.

*The Moderate/Low Phone Call algorithm requires the incorporation of data on how long the R has spent in each PPG. The R can spend up to a total of four months in the High PPG before being assigned to the Moderate/Low PPG and up to a total of nine months in the Moderate/Low PPG before being assigned to the Extra Low PPG. The R can spend up to the entire recruitment period in the extra low group, which receives phone calls once every six months. The R can also move back up to the Moderate/Low PPG and between the Moderate/Low PPG and Extra Low PPG groups based on the combination of their questionnaire answers and PPG history. The amount of time allowed in the High PPG resets after the birth of a new baby or the loss of a pregnancy.

**If eligible female reports that she is probably pregnant, her pregnancy will be verified at the time that her T1 visit is scheduled.

***First and last eligible due dates are based on the dates that screening starts and ends in each segment.

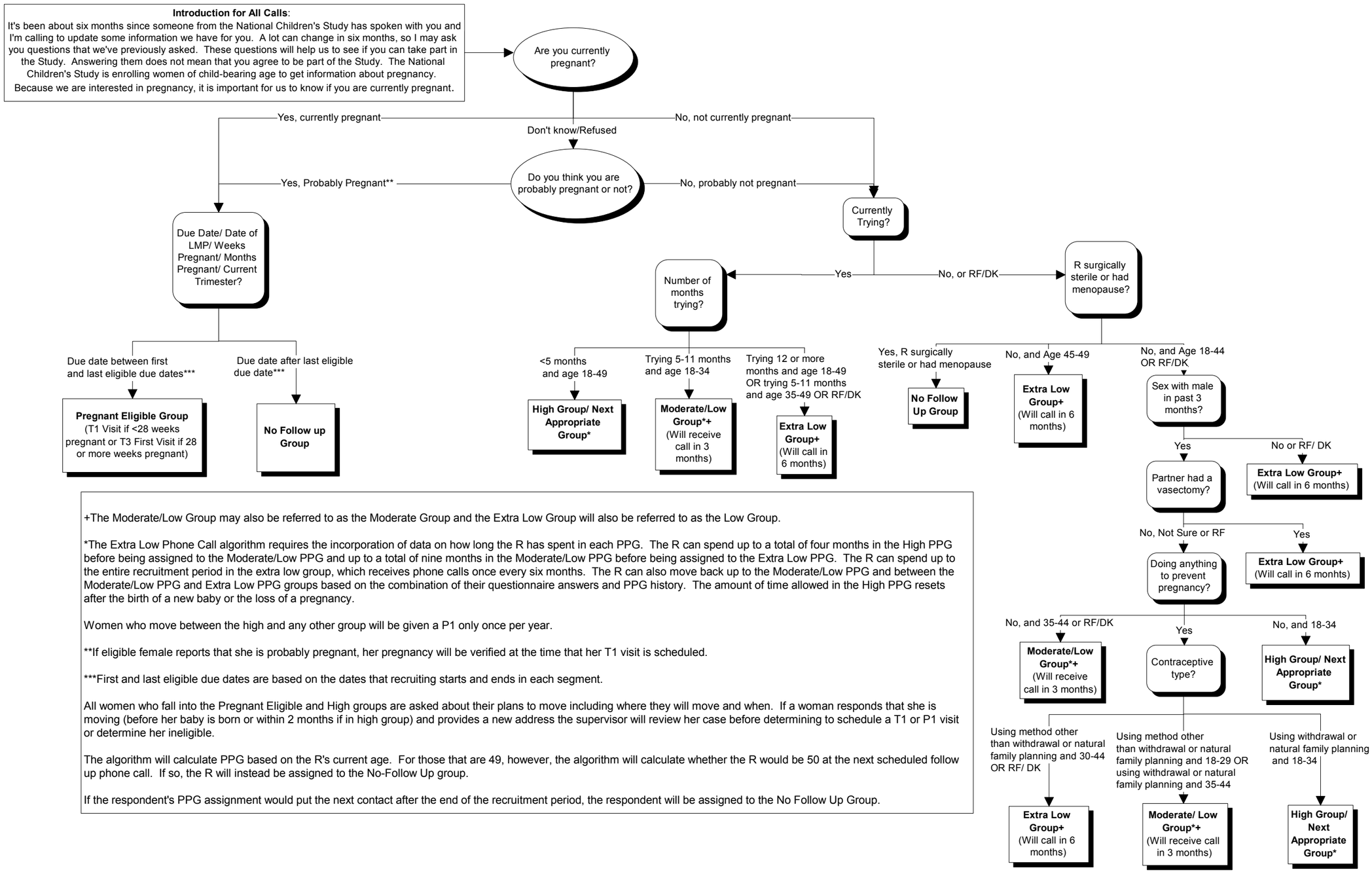
All women who fall into the Pregnant Eligible and High groups are asked about their plans to move including where they will move and when. If a woman responds that she is moving (before her baby is born or within 2 months if in high group) and provides a new address the supervisor will review her case before determining to schedule a T1 or P1 visit or determine her ineligible.

Women who move between the high and any other group will be given a P1 only once per year.

At the end of the recruitment period, all respondents who are not pregnant will be assigned to the No Follow Up Group. They will be informed that recruitment is ending and that they will not be contacted again.

The algorithm will calculate PPG based on the R's current age. For those that are 49, however, the algorithm will calculate whether the R would be 50 at the next scheduled follow up phone call. If so, the R will instead be assigned to the No-Follow Up group.

# Extra Low Call Algorithm 01.10.08+




+The Moderate/Low Group may also be referred to as the Moderate Group and the Extra Low Group will also be referred to as the Low Group.

*The Extra Low Phone Call algorithm requires the incorporation of data on how long the R has spent in each PPG. The R can spend up to a total of four months in the High PPG before being assigned to the Moderate/Low PPG and up to a total of nine months in the Moderate/Low PPG before being assigned to the Extra Low PPG. The R can spend up to the entire recruitment period in the extra low group, which receives phone calls once every six months. The R can also move back up to the Moderate/Low PPG and between the Moderate/Low PPG and Extra Low PPG groups based on the combination of their questionnaire answers and PPG history. The amount of time allowed in the High PPG resets after the birth of a new baby or the loss of a pregnancy.

Women who move between the high and any other group will be given a P1 only once per year.

**If eligible female reports that she is probably pregnant, her pregnancy will be verified at the time that her T1 visit is scheduled.

***First and last eligible due dates are based on the dates that recruiting starts and ends in each segment.

All women who fall into the Pregnant Eligible and High groups are asked about their plans to move including where they will move and when. If a woman responds that she is moving (before her baby is born or within 2 months if in high group) and provides a new address the supervisor will review her case before determining to schedule a T1 or P1 visit or determine her ineligible.

The algorithm will calculate PPG based on the R's current age. For those that are 49, however, the algorithm will calculate whether the R would be 50 at the next scheduled follow up phone call. If so, the R will instead be assigned to the No-Follow Up group.

If the respondent's PPG assignment would put the next contact after the end of the recruitment period, the respondent will be assigned to the No Follow Up Group.

Appendix C.4

60-Day Federal Register Notice

ANNUALIZED BURDEN TABLE

| Type of respondents | Estimated number of respondents | Estimated number of responses per respondent | Average burden per response | Estimated total annual burden hours requested |
|---|---|---|---|---|
| Asthma grantee survey | 1550 | 1 | .25 | 387.5 |
| Total | | | | 387.5 |

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Jerry Phelps, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–21, 111 T.W. Alexander Drive, RTP, NC 27709. Phone (919) 541–4259. E-mail: *phelps@niehs.nih.gov*.

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: November 7, 2007.

**Marc Hollander,**

*NIEHS, Associate Director for Management.*

[FR Doc. E7–22594 Filed 11–16–07; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Child Health and Human Development; Proposed Collection; Comment Request; Pilot Study for the National Children's Study

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Pilot Study for the National Children's Study, *Type of Information Collection Request:* NEW, *Affected entities:* Households and individuals. *Types of respondents:* People potentially affected by this action are pregnant women, women age 18–49 years of age, their husbands or partners, and their children who live in selected areas within the seven (7) National Children's Study Vanguard sites enumerated below. A small number of health care professionals, community leaders, and child care personnel are also potential respondents. *Frequency of Response:* On occasion. See burden table for estimated number of annual responses for each respondent. *Need and use of information collection:* The purpose of this Study is to pilot test protocols, policies, and procedures for the National Children's Study (NCS) with the goal of improving the efficiency of study procedures and enhancing the subsequent implementation of the NCS. The NCS is a long-term cohort study of environmental influences on child health and development authorized under the Children's Health Act of 2000. The Act specifies a broad definition of environment, including biologic, chemical, physical, and psycho-social factors and authorizes NICHD to plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of those exposures on child health and human development. This data collection will test procedures for population-based sampling and recruitment of pregnant women and women of child-bearing age, test study logistics, and estimates of subject burden, and evaluate data collection strategies including interviews and acquisition of biologic and environmental samples. In addition, participants will also be asked to provide qualitative and quantitative input on their feelings regarding participation in this Study, to enhance the lessons that can be learned and applied to improve the efficiency of the full NCS. Further details pertaining to the NCS background and planning, including the NCS Research Plan, can be found at: *http://nationalchildrensstudy.gov.* This Pilot Study will be carried out in the seven NCS ''Vanguard'' locations previously selected as the initial study sites. These sites are Orange County, CA; Duplin County, NC; Queens County, NY; Montgomery County, PA; Salt Lake County, UT; Waukesha County, WI; and the aggregate of Lincoln, Pipestone, and Yellow Medicine Counties, MN and Brookings County, SD. This data collection is intended to begin with household enumeration and enrollment of women, proceed through pregnancy and birth, and continue with follow-up of children for up to 21 years. This application is for the first three years of data collection, which includes data collection through the visits at which some of the children will be 24 months old. Details of data collections beyond this period will be addressed at the time of renewal or in future applications. Women who are pregnant will be eligible for participation if, at the time of household enumeration and screening, they are within the first trimester of pregnancy. Women who are not pregnant will be eligible if, at the time of household enumeration and screening, they are 18–49 years of age, are neither surgically nor medically sterile, and can participate in the consent process. A subset of age-eligible women with a high likelihood of pregnancy (*e.g.,* planning to become pregnant) will be enrolled to enable assessment of peri-conceptional

exposures, should they become pregnant. The remainder of the study population will comprise women enrolled early in pregnancy. The seven centers combined will follow approximately 1000 infants born to women enrolled in the first year of this Pilot Study. Infants born to women enrolled in this Pilot Study but born after the eligibility period for the Pilot will be eligible for enrollment in the full NCS. The schedule of participant contacts for this data collection includes home visits, clinic visits, and phone contacts, and is described in the NCS Research Plan: *http://nationalchildrensstudy.gov.* Home visits before and during pregnancy will include collection of interview data, environmental specimens such as air and dust samples, maternal and paternal biospecimens such as blood and hair samples, and a brief physical examination including anthropometric measures and blood pressure. During pregnancy, women will receive up to three fetal ultrasounds to assess fetal growth. At birth, cord blood and placental samples will be collected and the infant will receive a brief developmental assessment. During infancy, home visits will include collection of interview data, environmental specimens, biospecimens from the infant and parents, a brief physical examination of the infant, and assessment of infant development and parental-infant interactions. *Burden statement:* The public burden for this Study will vary depending on the eligibility and pregnancy status of potential participants at the time of household screening. Women who are not pregnant at the time of screening will have varying burden depending on their likelihood of pregnancy and, should they become pregnant, the time to pregnancy. The burden for women enrolled during pregnancy will depend on when during pregnancy they are identified and enrolled in the Study. The table provides an annualized average burden per person for each stage of the Pilot Study over the three year period of the Study.

ESTIMATED AVERAGE ANNUAL BURDEN FOR PILOT STUDY FOR NATIONAL CHILDREN'S STUDY, BASED ON THREE YEAR TOTALS

| Types of respondents (estimated hourly rate) | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours |
|---|---|---|---|---|
| Household activities ($12/hr): | | | | |
| Household enumeration | 76,911 | 0.33 | 0.08 | 2,051 |
| Eligibility screening | 45,316 | 0.33 | 0.08 | 1,208 |
| Preconception activities ($12/hr): | | | | |
| High probability women | 4,117 | 1.33 | 1.15 | 6,285 |
| Moderate prob, women | 5,500 | 1 | 0.08 | 458 |
| Low probability women | 3,578 | 0.33 | 0.08 | 95 |
| Pregnancy activities—women ($12/hr) | 954 | 7 | 0.62 | 4,134 |
| Birth activities—mothers & children ($12/hr) | 912 | 2 | 0.38 | 684 |
| Postnatal activities—mothers & children ($12/hr) | 893 | 4 | 0.81 | 2,887 |
| Fathers ($12/hr) | 954 | 2 | 0.72 | 1,370 |
| Health care providers ($90/hr) | 500 | 0.33 | 0.05 | 8 |
| Community leaders ($75/hr) | 500 | 0.33 | 0.05 | 8 |
| Child care providers ($25/hr) | 364 | 0.33 | 1.00 | 121 |
| Total | *79,229 | ..... | ..... | 19,209 |

*Total number of respondents is less than the sum of the column since the mothers will be identified in the household enumeration and screening.

The estimated annualized cost to respondents is $234,488 based on the differential hourly rate estimates in the above table. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Kenneth C. Schoendorf, MD, MPH, National Institute of Child Health and Human Development, Building 6100, 5C01, 6100 Executive Blvd, Bethesda, Maryland, 20892, or call non-toll free number (301) 594–9147, or e-mail your request, including your address to *ncsinfo@mail.nih.gov.*

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: November 6, 2007.

**Paul Johnson,**

*NICHD Project Clearance Liaison, National Institutes of Health.*

[FR Doc. E7–22597 Filed 11–16–07; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Emerging Neuroscience and Training Integrated Review Group.

The Emerging Neuroscience and Training Integrated Review Group shall

# Appendix C.5

# Outside Groups Consulted

**Federal Advisory Committee**

11/19/2007

**National Children's Study Federal Advisory Committee**

The National Children's Study Federal Advisory Committee, constituted under the Federal Advisory Committee Act, provides advice and recommendations to the Director of the National Children's Study, the Director of the National Institute of Child Health and Human Development, and the Interagency Coordinating Committee regarding critical aspects of the Study.

There are currently three designated National Children's Study Advisory Committee subcommittees: Scientific Review, Ethics, and Community Engagement.

The National Children's Study Federal Advisory Committee meets approximately three times a year. These meetings are open to the scientific community and the general public.

Charter

## Roster of Members

Alan R. Fleischman, MD (Chair)
Senior Vice President and Medical Director
March of Dimes

Kate (Costella) Winseck, MSW (Executive Secretary)
Outreach and Communications Coordinator, National Children's Study

Jessica N. Sapienza, MHS (Committee Liason Officer)
Adjunct Studies Program Analyst, National Children's Study

John L. Butenhoff, PhD, CIH, DABT
Medical Department
3M Company

Robert E. Chapin, PhD
Investigative Developmental Toxicology Lab
Pfizer Global Manufacturing Plant

Frank A. Chervenak, MD
Department of Obstetrics and Gynecology
Weill Medical College of Cornell University and NewYork-Presbyterian Hospital

Janet Currie, PhD
Department of Economics
Columbia University

Nancy Neveloff Dubler, LLC
Department of Epidemiology and Population Health
Albert Einstein College of Medicine of Yeshiva University

Helen DuPlessis, MD, MPH
Center for Healthier Children, Families, and Communities
University of California, Los Angeles

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Faculty Emeritus, Department of Pediatrics
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Department of Clinical Obstetrics, Gynecology, and Reproductive Sciences
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Myron Genel, MD
Professor Emeritus of Pediatrics
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Richard Guzman, MSW, MPH
Community Health and Social Services Center

James N. Jarvis, MD
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Michael Lebowitz, PhD
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Liliana J. Lengua, PhD
Department of Psychology
University of Washington

Bruce Levin, PhD
Department of Biostatistics
Columbia University Mailman School of Public Health

Jeffrey Long, PhD
Department of Human Genetics
University of Michigan School of Medicine

Barbara Anne Nabrit-Stephens, MD, MBA, FAAP
Care Management
Blue Cross Blue Shield of Florida

Gary Q. Peck, MD, FAAP
General Pediatric/Adolescent Medicine Physician

Robert C. Pianta, PhD
Center for Advanced Study in Teaching and Learning
University of Virginia

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Department of Epidemiology and Biostatistics
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Department of Health Policy and Administration
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David J. Schonfeld, MD
Division of Developmental Disabilities
Cincinnati Children's Hospital Medical Center

Peggy M. Shepard
West Harlem Environmental Action, Inc. (WE ACT)

Alan M. Zaslavsky, PhD
Department of Health Care Policy
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Duane F. Alexander, MD (ex officio member)
Director
National Institute of Child Health and Human Development
National Institutes of Health, DHHS

Allen Dearry, PhD (ex officio member)
Associate Director, Research Coordination, Planning, and Translation
National Institute of Environmental Health Sciences
National Institutes of Health, DHHS

Kevin Y. Teichman, PhD (ex officio member)
Acting Deputy Assistant Administrator for Science
Office of Research and Development
U.S. Environmental Protection Agency

Edwin Trevathan, MD, MPH, FAAP (ex officio member)
Director, National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention, DHHS

Page updated - 11/19/07

## Interagency Coordinating Committee

The Interagency Coordinating Committee organizes and directs operations of the Study. This committee is made up of staff from two federal agencies: the U.S. Department of Health and Human Services (DHHS) and the U.S. Environmental Protection Agency (EPA). Within DHHS, staff is contributed from the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). CDC contributes staff from the National Center on Birth Defects and Developmental Disabilities and the National Center for Health Statistics; NIH contributes staff from the National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences. EPA contributes staff from the National Center for Environmental Research, the National Health and Environmental Effects Research Laboratory, the Office of Children's Health Protection, and the National Exposure Research Laboratory.

### Interagency Coordinating Committee Members

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National Center on Birth Defects and Developmental Disabilities, CDC, DHHS

Page updated–09/11/07

# Steering Committee

## Steering Committee

The National Children's Study Steering Committee consists of one voting member from each of the Vanguard Centers; the National Children's Study Director, who is also the Chair of the Steering Committee; the two Co-Project Officers of the Coordinating Center and Vanguard/Study Centers; and two voting members from the Interagency Coordinating Committee.

## Steering Committee Members

Ruth Brenner, MD, MPH
National Children's Study Program Office, NICHD, NIH, DHHS

Edward B. Clark, MD
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James Swanson, PhD
Child Development Center, University of California, Irvine

Ruth Thomson, MPH
Westat

Updated - 01/17/08

## Other Study Supporters

### Study Supporters

The following organizations have expressed their support for the National Children's Study:

Allergy and Asthma Networks Mothers of Asthmatics
Alpha Kappa Alpha Sorority, Inc.
Ambulatory Pediatric Association
American Academy of Pediatrics
American Academy of Sleep Medicine
American Association for Clinical Chemistry
American Association on Intellectual and Developmental Disabilities
American Chemistry Council
American College of Obstetricians & Gynecologists
American Educational Research Association
American Pediatric Society
American Psychological Association
American Public Health Association
American Society for Bone and Mineral Research
American Society for Pediatric Nephrology
American Speech-Language-Hearing Association
Association of American Medical Colleges
Association of Medical School Pediatric Chairs
Association of University Centers on Disabilities
Association of Women's Health, Obstetric and Neonatal Nurses
Catholic Health Initiatives
Children's Environmental Health Network
Coalition of Heritable Disorders of Connective Tissue
Center for Children's Health and the Environment, Mount Sinai School of Medicine
Consortium of Social Science Associations
Cooley's Anemia Foundation
Easter Seals
First Candle/SIDS Alliance
Genetic Alliance
Jeffrey Modell Foundation
Learning Disabilities Association of America
March of Dimes
National Association of Boards, Commissions and Councils of Catholic Education of the National Catholic Educational Association
National Association of Counties
National Association of County and City Health Officials
National Association of Pediatric Nurse Practitioners
National Black Child Development Institute
National Catholic Rural Life Conference
National Center for Learning Disabilities
National Coalition of 100 Black Women
National Council of Catholic Women
National Education Association
National Family Planning and Reproductive Health Association
National Healthy Mothers, Healthy Babies Coalition

National Hispanic Medical Association
National Medical Association
National Parent Teacher Association
National Rural Health Association
Safe Kids Worldwide
Osteogenesis Imperfecta Foundation
Population Association of America
PXE International
Society for Maternal Fetal Medicine
Society for Pediatric Nephrology
Society for Pediatric Research
Society for Research in Child Development
Society for the Study of Reproduction
Spina Bifida Association of America
The Arc of the United States
The Catholic Health Association of the United States
The Teratology Society
United Cerebral Palsy
United States Conference of Catholic Bishops

Page updated - 04/06/07

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# Appendix C.6

# Incentive Plan

## NCS

## Proposal for Incentives (not including expense reimbursements)

| | P1 Home Visit | P1 mo. High Phone | P2 mo. High Phone | P4 mo. High Phone | P-Moderate | P-Low | T1 First / Prior Home Visit | T1 Ultrasound (U/S) (if needed) | T 16-17 wk. Phone | T2 U/S | T3 Clinic Visit | T3 U/S (if separate visit required) | T36 wk. Phone |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **In-person interview, Environmental, Biospecimens, and/or Physical measures, and/or Leave-behinds** | $100 total, $80 after interview and technical collection $20 at receipt of self collection [1] by cash or check [2] | | | | | | $100 total mother, $100 total father, $80 after interview and technical collection $20 after receipt of self collection | | | | $100 total, $80 at end of clinic visit, $20 at receipt of self collection | | |
| **Telephone interview only** | | None | Non-cash incentive for mother mailed after call | None | None | None | | | None | | | | None |
| **Mailed request for SAQ or other (no in-person contact)** | | | | | | | | | | | | | |
| **Ultrasound only** | | | | | | | | None | | None | | None | |

| | B1 Plus B2 Mother/Child (Hospital) | 1 mo. (only if no B1 Plus B2) Home Visit | 3 mos. Phone | 6 mos. Home Visit | 9 mos. Mom Phone | 9 mos. Dad Phone | 12 mos. Home Visit | 18 mos. Mom Phone | 18 mos. Dad Self Collection | 24 mos. Phone |
|---|---|---|---|---|---|---|---|---|---|---|
| **In-person interview, Environmental, Biospecimens, and/or Physical measures, and/or Leave-behinds** | mother - cash incentive at receipt of self collection [3] ---------- child - non-cash baby item given at discharge [3] | See B1 Plus B2 for mother/child | | $100 total mother, $20 total father, ---------- mother-$80 after interview and technical collection $20 at receipt of self collection, ---------- father-$20 at receipt of self collection, ---------- child-non-cash baby item after measurements taken | | | $100 total mother, $100 total father, ---------- mother/father - $80 after interview and technical collection $20 at receipt of self collection, ---------- child - non-cash baby item at the end of visit | | | |
| **Telephone interview only** | | | None | | None | None | | None | None | $40 mailed at receipt of self collection |
| **Mailed request for SAQ or other (no in-person contact)** | | | | | | | | | None | |

[1] Defined as receipt of SAQs/self collected samples

[2] VCs can choose to distribute each cash incentive as cash or by check

[3] Cash and non-cash incentive combined will total $50.00

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# Appendix C.7

# Certificate of Confidentiality

**Certificate of Confidentiality**

# (To come)

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# Appendix C.8

# Sampling and Recruitment Plan

# SAMPLING AND RECRUITING PLAN

## 1 Sampling Strategy

A number of study and sampling design options were considered for the NCS (see Sample Design Options and other related documents available at http://www.nationalchildrensstudy.gov/events/advisory_committee/other_work_062004.cfm). There are advantages and disadvantages to each of the candidate approaches; however, after careful consideration and upon the advice of the NCSAC, a national probability sample of all U.S. births was chosen as the design that best fulfills the following goals:

- Collection of high quality, objective data to minimize measurement biases
- Avoidance of selection biases and other biases that could lead to invalid inferences concerning exposure/outcome relations
- Ability to capture the diversity of the U.S. population such that both the range and diversity of exposures and outcomes are represented
- Ability to generalize results of the NCS to the U.S. population.

The sample design for the NCS is a multistage probability sample of births in the United States where the births are identified from a sample of households. The design includes two or three stages of sampling.

The first stage of sampling was the selection of primary sampling units (PSUs), which correspond to single counties or groups of contiguous counties. The second stage is the selection of smaller geographic areas (segments) from within the primary sampling unit. In general, these segments comprise city or suburban blocks or combinations of blocks and roughly correspond to neighborhoods. The third stage, which applies only to very densely populated segments, involves the selection of groups of households from within the segments. Each stage is detailed in the following subsections.

### 1.1 Selecting Study Locations

The process for selection of Study locations was based on the need to achieve representative coverage of the United States with respect to geographic areas, metropolitan/nonmetropolitan areas, and demography. All decisions on sample design options considered costs, coverage, statistical reliability, and practical concerns of the protocol. Cost models and logistical aspects of the NCS data collection led to the design decision to use 105 study locations.

The probability of a county being selected as a PSU is based on the number of births to residents of that county. Because the number of births in a county at a future date cannot be known, data on resident births (births based on the mother's residency at the time of birth) from four recent years (1999–2002, the most recent 4-year period available at the time) were used as an estimated measure of size for sampling the PSUs.

The 3,141 U.S. counties were categorized into 18 large strata defined by metropolitan status (metro, nonmetro) and geography (nine census divisions). Within each of the 18 large strata, the total number of births determined the initial number of smaller strata. Based on their number of births, 13 counties were large enough to be designated as self-representing units (also referred to as certainty units).

For three of these counties, the number of births was so large that each county was assigned multiple PSUs. Los Angeles County was assigned four PSUs; Cook County, IL, (containing Chicago) was assigned two; and Harris County, TX, (containing Houston) was assigned two. These are units that were "certain" to be selected into the probability sample based on their large number of births. Thus, the design contains 13 locations but 18 PSUs that are considered self-representing.

The remaining 3,128 counties were placed into smaller strata. Within each of the 18 large strata, these smaller strata were formed to be of roughly equal size. The smaller strata were defined in terms of the size of county or the percent of births with specific characteristics. The characteristics used to define the smaller strata were percent of births to Native American women, percent of births to Asian women, percent births to Hispanic women, percent of births to Black women, and percent of low birth weight. After all strata had been formed, one PSU per strata was selected with a probability proportional to size (i.e., number of births).

A minimum measure of size for a PSU was established as 2,000 births during a 4-year period (or an average of 500 births per year). If a county was selected that had fewer than 500 births per year, geographically adjacent counties in the same stratum were added until the PSU met the minimum measure of size. In a few cases, that criterion could not be achieved. For such cases, an additional PSU was selected.

The final first stage sample comprised 110 PSUs in 105 locations: 26 locations are non-self-representing PSUs from nonmetropolitan strata, 66 locations are non-self-representing PSUs from metropolitan strata, and 13 locations with 18 PSUs are from self-representing metropolitan strata. Although this design is generally consistent with an equal probability sample design, differences in the sizes of the strata relative to the PSU probability of selection results in some variation.

### 1.2 Sampling within Locations (PSUs)

To meet the analytic needs of the Study, a total sample size of 1,000 enrolled live births is the target for each sampled PSU. With an enrollment period of 4 years, a sample size of 250 enrolled live births per year in each PSU is needed. (The Vanguard Centers have an additional year of enrollment and thus have 1,250 targeted births.) Because each selected PSU has greater than 250 births expected per year, a sample of births within each PSU must be designed and selected. This leads to the second stage of selection for the NCS. It is not feasible to take a simple random sample of births within each PSU. The second stage of the NCS design consists of forming small geographic units within a PSU called segments (or secondary sampling units) and then selecting a sample of those segments for inclusion into the Study.

### 1.3 Segment Sampling

To increase the operational efficiency, reduce costs, and provide for more useful representation of neighborhood-level characteristics, the segments within the PSUs are "clusters" of households. A geographic classification used by the U.S. Census Bureau (blocks nested with block groups, block groups nested within census tracts) is used to form segments. An advantage of using census geography is that data from other sources for these units can be linked to the sampled segments.

Prior to the formation of segments in a PSU, a target number of sampled segments is established. This number is primarily based on operational considerations and varies between PSUs. For most PSUs, it is expected that the number of sampled segments will be between 10 and 15. In general, a smaller number of segments are targeted in more rural, less densely populated PSUs that cover large areas; in more densely populated PSUs with larger numbers of births, the number of sampled segments

may be larger. The segments are constructed to be as uniform in size as possible within a PSU, but slight departures from the target segment size are expected.

As was done for the selection of PSUs, segments will be stratified to improve the precision of estimates and to ensure the sample is representative with respect to the stratum definitions. The NCS segments will be formed by combining a number of census blocks or block groups. Stratification can be done either before or after segments are formed. When stratification is done beforehand, the characteristics of the block groups can be used to form strata and only block groups in the same strata are then combined to form segments. These segments are homogenous with respect to the stratification variables but may not be geographically contiguous, thus increasing data collection costs. When stratification is done afterward, contiguous block groups can first be clustered to form segments and then "similar" segments are grouped to form strata.

It is expected that the segment stratification scheme will vary from PSU to PSU, with a goal of achieving locally defined neighborhoods as segments. (It is hoped that using locally defined neighborhoods will increase study participation rates and facility data collections at the community level.) Within most PSUs, geographic stratification will be used either as the sole stratifying variable or in combination with other variables. Geographic stratification is useful because many of the characteristics that differentiate subpopulations (such as income, race/ethnicity, educational attainment, and environmental measures) tend to be geographically clustered.

The strata are formed as equal in size as possible so that with approximately equal-sized segments, an approximately equal probability sample of segments is obtained. In some cases, it is desirable to allow for some variations in stratum sizes within a PSU to construct more homogenous strata than an equal-sized-strata scheme would permit. If the strata vary in size within a given PSU, the segments also vary in size across strata to equalize the sampling fraction within each stratum. For example, if one stratum is twice as large as another stratum within a given PSU, the segments within the first stratum are constructed to be twice as large as the segments within the second stratum.

In some cases, the strata are not geographically contiguous. This is typically the case when variables other than geography are used for segment stratification. In these cases it is necessary that each disjointed part of a stratum be large enough to form complete segments with minimal variation in segment size.

One challenge in having PSUs that have different sizes (number of births) is the large variation in the number of possible segments across PSUs. For example, among the Vanguard Centers, the smallest PSU has only 11 segments whereas the largest has approximately 18,000 (in the population not the sample). A large number of segments causes difficulties in both forming and reviewing segments. In order to use resources more efficiently, a three-stage sampling protocol is used for large PSUs (typically those with more than 500 segments).

In large PSUs, geographic units are formed within strata and these geographic units, which vary in the total number of estimated births, are sampled with the probability of selection proportionate to the size of the geographic unit. Within each stratum, exactly one geographic unit is selected. Segments are then formed within the sampled geographic unit to be equal in size. Across strata, the segments are made equal in size if the strata are equal sized, or vary in size proportionate to the variation in stratum sizes if the strata are not equal sized. Within each sampled geographic unit, exactly one segment is randomly selected.

## 1.4 Listing and Enrollment

In selected segments, household screening is attempted in all households (dwelling units; DUs) in the segment. The exception is a very large segment, which cannot be subdivided during segment formation. In such segments, DUs are subsampled. If one of these large segments is selected, the segment is divided into "chunks" and then a chunk is randomly sampled for listing and enrollment. For example, suppose a given segment is twice as large as the target segment size and consists of two very large apartment buildings that contain approximately equal numbers of DUs. In that case, each apartment building is a chunk, and one of the two is randomly selected to be retained in the sample. Other approaches for chunking (depending on the situation) include using floors of apartment buildings or block faces as chunks.

Household screening is attempted in each sampled DU, and all eligible women are enrolled. The scheduled monitoring of eligible women is dependent on each woman's likelihood of becoming pregnant. Women more likely to become pregnant are contacted more frequently. In some instances, the composition of the household will change or the DU will have new occupants. To enroll births from mothers in these situations, all DUs will be contacted at least once a year. This contact will be used to update the status of enrolled women's likelihood of pregnancy and thus her schedule for follow-up visits.

## 1.5 Rollout of PSUs

A sample of seven PSUs was selected to serve as the Vanguard Centers. These seven Vanguard Centers will serve as a platform to develop methodologies and procedures that will be refined and implemented throughout the Study. The remaining 98 PSUs will be introduced in three waves. The specific plan for the subsampling of the PSUs into the waves is currently under consideration. Pilot data collection is planned to begin in the Vanguard Centers in mid-2008, data collection in the first wave of additional PSUs is planned to begin in mid-2009 with the second wave 2 years later and the final wave 2 years after that.

The 98 PSUs not covered by the Vanguard Centers will be covered in the subsequent waves by the addition of Study Centers. Each Study Center will oversee participant recruitment and data collection at one to three geographically proximal study locations. The Vanguard Centers and Study Centers will work with the NCS Coordinating Center and the NCS Program Office to ensure effective development and implementation of study procedures.

## 1.6 Subsamples

In addition to the core set of measurements collected from all study participants, a number of data collections are being considered that involve collection of survey information, samples, or biological specimens from a subset of the total population or only at the community level. One example would be to reduce the proportion of samples obtained with nonmeasurable concentrations of an environmental substance. Questionnaire information on recent pesticide applications could be used to determine what homes will have air samples collected for nonpersistent pesticides since the air concentrations of these chemicals tend to decrease over time. Pesticide measurements in drinking water currently are being planned only in rural areas for homes using private wells because municipal water system information would be available for other locations and pesticide concentrations in drinking water in urban areas often are below detection limits. In some cases, environmental samples will be collected but not analyzed (e.g., metals in dust) unless biomarker concentrations (e.g., blood levels) indicate higher exposures have occurred, and there is a need to determine the media or sources contributing to this exposure. Additionally, the large sample size of the National Children's Study affords the opportunity for more in-depth studies of subsamples within the framework of the longitudinal cohort study. Finally, to optimize

the study's ability to incorporate state-of-the-art measurements, including some too costly or too burdensome for implementation in a sample of 100,000, the use of a validation sampling approach might be considered for certain measures. In this approach, a simple or less costly assessment is paired with the more costly or burdensome approach in a planned subsample of the population. For example, personal monitoring may be the best way to measure direct exposure to air pollutants or pesticides, but the cost and intrusiveness of this monitoring make this impractical to use on the entire cohort. The relation between the two assessments of the same domain is used to characterize and adjust for "measurement error" in the analysis of exposure-outcome relations for the entire cohort, although the majority of the study participants receive only the simpler, less expensive assessment. Similarly, a matrix approach for other applications (e.g. varying times of assessment) is also being considered.

For the initial year of data collection in the Vanguard sites, we also have developed plans to subsample women who are identified as having the greatest chance for becoming pregnant. The general plan is that all women in this category will be scheduled for the initial in-person visit to collect prenatal data. Since there are several factors that may cause the number of women in this group to vary and these factors can only be modeled at this time, a subsampling scheme will be implemented in a PSU if the number of women identified for the visit is larger than the data collection capacity. The subsampling may differ by the characteristics the women report in the pregnancy screening interview. No subsampling for the prenatal visits will be done in any site unless the expected number of women sampled for the visits becomes too large.

## 2 Participant Recruitment

### 2.1 Recruitment Goals

The goal of recruitment is to obtain the highest response rate possible to reduce the potential for nonresponse bias. The minimum goal for combined response and coverage in each location will be between 65–75 percent. Study locations with traditionally lower survey participation rates will have lower targets. For example, in highly urban areas response rates for surveys are often considerably lower than in other settings.

To assess the impact of nonresponse bias, studies will be undertaken to assess the differences between responders and nonresponders. Lower response rates are acceptable only if it can be demonstrated that the nonrespondents are missing at random, or if a nonresponse assessment provides an adequate statistical procedure to adjust NCS estimates for nonrandom missingness. This combination of rigorously conducting the Study to obtain response rates as high as feasible along with studying the characteristics of nonrespondents is consistent with new standards and guidelines developed and distributed by the Office of Management and Budget.

### 2.2 Enumeration of Households

Within selected segments, all households will be enumerated to identify women of child-bearing age living in the household. This enumeration will be conducted in person by trained interviewers using computer-assisted personal interviewing techniques. An adult household reporter (age 18 or older) will be asked to answer questions about the number of household members, the number of males and females, and for females, their ages and their relationships to the household reporter. To ensure coverage of all dwelling units within each structure, questions will also be asked about other dwelling units that may not be easily visible or obvious, and therefore may have been missed during the listing process.

Two groups of age-eligible women (18–44) are targeted for enrollment: women who are in their first trimester or pregnancy and women who are at some probability of becoming pregnant during

the 4-year enrollment period. After the age-eligible women are identified from the household enumeration, a separate pregnancy screener will be completed with each woman to determine her status. This will be done using a standardized set of questions related to her age, history of prior births, contraceptive use, and sexual activity. To ensure privacy these questions the pregnancy screener will be administered in-person using computer-assisted self-interviewing techniques, which allow the woman to enter her responses directly into the computer. An audio feature of this will be included to read the questions to the woman to further ensure privacy and to circumvent possible literacy issues.

Women who are not currently pregnant and who are not actively trying to become pregnant, or who are trying to become pregnant but based on the pregnancy screening have a relatively low probability of becoming pregnant, will be categorized as either "low probability" or "moderate probability." These groups will receive periodic phone contacts to determine if they have either become pregnant or, based on a limited set of screening questions, have moved to the group at higher probability of pregnancy. Women who are at high probability of becoming pregnant will be enrolled in the preconception cohort and actively followed for four menstrual cycles following enrollment. It is estimated that 55.2 percent of women in this group will become pregnant during this timeframe.

There will be periodic rescreening of households in selected segments to monitor for "move-ins" and other changes in the composition of the household living at each address. This periodic rescreening will take place only for those households where no eligible women are identified (estimated to be approximately 70 percent of all households). For those households with women being followed as part of the Study, scheduled contacts will be used to update information about household membership. This will be an important mechanism for monitoring changes in household composition as well as for identifying young women who "age in" (i.e., turn 18) during the 4-year enrollment period.

### 2.3 Recruitment through Prenatal Care and Other Mechanisms

The primary mechanism for recruiting women for the Study is by contacting them in their households and encouraging them to participate in all phases of the Study. Some women, however, will move into sampled segments after the segments have been screened (and prior to the recontacts discussed above). Since children born to women living in the sampled segments are eligible, other mechanisms are needed to identify and recruit these women.

A supplemental mechanism to recruit eligible women (those living in the sampled segments) is through providers of prenatal care, birthing centers, and hospitals. All of the requirements of those sampled in households must be satisfied by these women, so this is simply another technique for identifying and recruiting eligible women from sampled households. In addition to increasing the Study's ability to cover the mobile population that otherwise would be missed, this supplemental recruitment also provides another opportunity to encourage participation from women who previously chose not to participate in the Study when contacted in the household screening. While this method is useful in reducing nonresponse and undercoverage, it does not provide full data from the pre-pregnancy and early pregnancy data collections and is thus viewed as a supplemental approach.

## 3 Community Outreach and Engagement

The NCS values community engagement, but it will not follow a strict community-based participatory research model. Community-based participatory research is defined as a collaborative research approach designed to ensure and organize participation in all aspects of the research process and action, emphasizing participation by the communities affected by the issue being studied, by representatives of organizations, and by researchers. Because the protocol includes data collection from multiple study sites to answer specific study questions that require a national sample, it was not possible

to define the core study questions and initial protocol development through input of local communities or to account for their varied needs. However, principles of community-based research will be applied when feasible and appropriate. A partnership with each community will be formed to ensure mutual respect and the establishment of an enduring relationship. Genuine community engagement offers the hope of enhancing recruitment, retention, and participant satisfaction.

Since the beginning of planning, the NCS has undertaken a range of community engagement activities to lay the groundwork for Study Center activities. Between 2000 and 2005, the NCS conducted many focus groups to obtain community perspectives on informing communities about the NCS, gaining the support of communities, recruiting and retaining participants, and conducting NCS sampling and visits. Additionally, the establishment of working groups, the Study Assembly, and the Federal Advisory Committee allowed ongoing community input into the Study plans. The Vanguard Centers are working within local communities to prepare for recruitment. Study Centers will continually share experiences with and learn from each other in implementing community engagement plans.

Ideally, Study Centers will be able to build upon prior local community networks and relationships. However, the unique sampling strategy, data collection intensity, and length of the NCS necessitate different approaches to working with communities than previous studies or projects. To build trust, enhance the credibility of the Study, and ensure community engagement on the local level, the investigators from the Centers will conduct community needs assessments to identify children's environmental health issues in the target community during the first year of the Study. These assessments will focus on community concerns regarding the core NCS protocol and additional concerns (e.g., health issues) that may be considered for inclusion in the core protocol at all sites or as a specific sub-study focus in the particular site. Community activities will include identification of community representatives and resources and recruitment of community partners to facilitate engagement. Examples include advance contact with community leaders to gather information about the community, town meetings, and listening sessions. Key community members will be recruited and engaged in support of the Study in activities such as acting as a spokesperson for the Study, providing insight into local issues to enhance the relevance of the NCS for their community's health, and serving on community advisory boards. Reliance on secondary data sources like environmental and geographic data actually can enhance these activities. Previous studies have shown the importance of involving community members, either in the actual data collection for the study or as liaisons to special populations such as the medically underserved. These approaches will be utilized at the Study Centers to the extent possible.

Prior to the enrollment period, each Study Center will increase the awareness of the Study among community residents. Building on the community engagement efforts and involvement of community members described above, a variety of strategies will be used to announce the NCS enrollment period. Examples include press releases, appearances on local television and radio shows, and other methods to increase community excitement and interest. Wherever possible, these activities will involve joint participation of study staff and community members. These press and public relations activities will have the technical support of the Coordinating Center and the NCS Program Office, with the approval of the NCS Project Officer.

Throughout the Study, the Study Centers will involve and solicit input from the community. Examples of ongoing activities include establishing a community advisory board, partnering with other organizations to host events or forums, incorporating community leaders into the Study Center structure, and building referral networks between the Study and organizations. Steps for community engagement will vary depending on the characteristics and experiences of the communities and the Centers, and it is expected that the most effective approaches will vary. Once data collection begins, communities will be interested in learning about Study findings. Aggregate findings will be shared with individual participants and communities through newsletters, publications, and other means. The community perspective can

inform NCS researchers on ways to be sensitive to unique cultural and political issues and to concerns within each community when communicating results. Because the NCS is a long-term research effort, attention to sustaining community relationships will be very important.

# Appendix C.9

# Data Collection from Community Members/Medical Providers

## Motivation for participating in the NCS: Collecting feedback from participants in NCS community events and from respondents who enroll in the NCS

Objective:

The National Children's Study is committed to community engagement in the planning and implementation of the Study. Specifically, the November 2004 RFP to create Vanguard Centers recognized the importance of "identifying community resources and recruiting community partners to facilitate engagement," and required contractors to "develop and implement a plan for community participation and engagement to support recruitment and retention efforts for the Study."[1]

The Vanguard Centers will invest a lot of time and effort in organizing and implementing different types and numbers of community engagement activities with the hopes that these activities will build awareness and interest in the National Children's Study, ultimately facilitating enrollment. The objective of this evaluation is to collect information on what motivates women to enroll in the NCS, and whether the community outreach and promotion activities correlate to higher enrollment rates. Additionally, the evaluation will measure what factors contribute to continued participation in the study such as participant satisfaction with the NCS experience. Similarly, the evaluation will also ascertain whether higher retention rates in the study correlate with participation in and positive perceptions of the various community engagement activities.

As a secondary objective of this evaluation, measures of participant satisfaction with the NCS experience can be used to refine data collection procedures and training in the future. Additionally, these satisfaction measures can serve as a source of information to OMB in regards to the perceived burden of participating in this study.

High Level Research Questions:

1) How do participants in the various community outreach and promotion activities rate the activities in terms of improving their overall perception of the NCS and the NCS objectives?
2) How comfortable do participants feel voicing their personal opinions or participating in a dialogue at the various community outreach and promotion activities?
3) Do the ratings obtained from the outreach and promotion activities correlate with enrollment rates (at the VC) level?
4) Do either of the following measures differ between those who chose to enroll in the study and those who don't: reported participation in at least one NCS-sponsored activity, and awareness of the NCS prior to an interviewer contacting the household.
5) For women who chose to participate in the study, what factors influenced their decision to participate? Do these same factors influence their continued participation?
6) Does the respondent's reported experience with data collection activities influence their continued participation in the NCS?

[1] RFP. National Children's Study. NIH, NICHD. 2004. Available at: http://www.nationalchildrensstudy.gov/research/study_plan/index.cfm Accessed December 6, 2006

General Design

To address each of the research questions we will collect data at several different points. The following table shows each data collection point by research question. All data collections for this evaluation, except for one, will use a self-administered, paper questionnaire (SAQ). It is likely that respondents will feel more comfortable and will provide more honest feedback about their experience with the NCS if they are given the opportunity to respond privately using a self-administered questionnaire (SAQ), rather than providing feedback directly to the interviewer.

| Research Q Number. | When Collected | Who Participates | Method of Collection | Questionnaire |
|---|---|---|---|---|
| 1, 2, 3 | At close of NCS sponsored event | All event attendees asked to complete | SAQ completed and returned at event or mailed in a postage paid envelope provided at the event | Community Activities Engagement Questionnaire |
| 4 | At the screener interview | All women asked to complete the audio-casi pregnancy screener | Built as an intro to the pregnancy screener instrument but asked by the interviewer before starting the audio-casi instrument | Questions within the Pregnancy Screener |
| 5, 6 | At the end of each personal visit interview (P1, T1-first (pick-up visit), T3) | All enrolled women who complete some portion of the P1, T1, or T3 data collection | SAQ completed at the end of the visit. | Participant Evaluation Questionnaire. |

Evaluating Community Engagement Activities

Fully evaluating the community engagement activities requires two separate data collections. The first data collection, which covers the first three research questions, asks all participants of an NCS sponsored activity to evaluate the activity by completing a short, paper, self-administered questionnaire (SAQ). The NCS staff should hand out the SAQs to all attendees of the NCS sponsored event at some point during the activity, though the exact timing will vary depending on the forum. Regardless of when participants receive the SAQ, NCS staff should ask them to complete it and return it before leaving the event. If, however, the forum does not lend itself to completing the SAQ on site, the NCS staff should provide a postage paid return envelope along with the SAQ.

Since the community engagement activities will vary from Center to Center, the VCs will need to tailor the questionnaire to each activity for which evaluation data are needed. Specifically, the VC's will need to

- Label the questionnaire to identify the event covered by the evaluation,
- Add a unique identifier (ID number) to each questionnaire, and
- Add in the appropriate term or title for the event within the questions.

Additionally, the VCs will need to consider the best timing for distributing the questionnaire during the activity. The VC's will work with the program office to identify which community engagement activities will include the evaluation SAQ.

The second data collection effort in the evaluation of the community engagement activities will assess whether participation in the community events and/or awareness of the NCS prior to a visit from NCS staff influenced a person's decision to participate in the NCS (research question number 4). In answering this research question, the evaluation tool must collect data from both women who do and women who do not ultimately enroll in the study. Additionally, to understand the relationship between attendance at the NCS sponsored events and participation in the NCS, this data collection must include people who did and did not attend events. (Data collected at the close of NCS sponsored activities cannot speak to this question since those questionnaires will not include the necessary identifying information to link to respondents in the NCS.) Thus, these data will be collected as part of the pregnancy screening interview. When the screening interviewer identifies an age-eligible woman in a household, the interviewer will ask the woman a short set of scripted questions before starting the pregnancy screener. The screening instrument will include these questions just prior to the start of the audio-CASI portion of the interview minimizing any disruption in the flow of the interview. Since these questions do not explicitly evaluate the interviewer, the events or the data collection activity, respondents should feel comfortable providing responses to the interviewer directly (rather than using an SAQ).

To summarize, evaluating the community engagement activities will include two separate data collection components. First, data that speak to participant's perceptions of a specific activity will occur at the close of the activity (or at some other point in the activity identified by the VCs as more appropriate) using a paper self-administered questionnaire. Second, data that speak to whether awareness of the NCS or participation in any of the community engagement activities influence participation in the NCS will be collected by the NCS interviewer as part of the pregnancy screening interview. These two data collection efforts address research questions 1 through 4.

Evaluating NCS (Pilot) Data Collection Activities

Research questions 5 and 6 address what factors influenced a participant's decision to enroll in the study, as well as assess whether their experience with the study influences their continued participation. To answer these questions, the NCS will collect evaluative data from women who have enrolled in the study and completed at least one data collection visit using a short, paper, self-administered questionnaire (SAQ). The NCS interviewer can briefly explain the purpose of this questionnaire and ask the respondent to begin completing it as he/she begins the final visit close-out, including the collection of the environmental equipment. To the extent possible, the data collector should ask the respondent to complete this SAQ before giving the respondent the final visit payment. Women who do not complete every component of the visit (e.g., do not provide one of the biologic measures) still will be asked to complete this evaluation questionnaire at whatever point the interviewer begins the visit close-out activities.

Since the last research question includes assessing whether the respondents experience in the NCS data collection influences their continued participation, we suggest asking participants to complete the "Participant Evaluation Questionnaire" questionnaire after each of the personal visit data collections (P1, T1-first, T3), rather than at some set period of time after enrollment. Asking for this feedback at

particular data collection points will allow the analysis to control for different amounts and types of experience which could greatly influence how participants respond.

Each of the evaluation questionnaires are included on the following pages.

# QUESTIONNIARE ADDRESSING: EVALUATION OF COMMUNITY ENGAGEMENT ACTIVITIES

*VC puts label here that identifies NCS event and numbers the questionnaire*

**NATIONAL CHILDREN'S STUDY**
**Activities (Community Engagement Activities) Questionnaire**

Thank you for participating in this National Children's Study (NCS) Activity. We would appreciate you taking a few minutes to answer some questions about your overall impression of the NCS Activity. Your feedback will help us improve the National Children's Study for future phases of the Study in which you or your child may choose to participate. Please answer these questions to the best of your ability.

Completion of this form is voluntary and you can choose to complete it or not. If you do not complete it, your eligibility to participate in the National Children's Study will not be affected. As with all other activities, the information you provide will be kept confidential and used only for purposes of the Study.

**1. How did you hear about the National Children's Study?** (check all that apply)

| | Yes | No | Don't Know |
|---|---|---|---|
| a. Friends | _____ | _____ | _____ |
| b. Family | _____ | _____ | _____ |
| c. Church, Synagogue, or other places of worship | _____ | _____ | _____ |
| d. Community leaders | _____ | _____ | _____ |
| e. Someone else in my community (other than the National Children's Study researchers) | _____ | _____ | _____ |
| f. Your doctor or health care provider | _____ | _____ | _____ |
| g. Newspaper, TV, radio | _____ | _____ | _____ |
| h. Billboard | _____ | _____ | _____ |
| i. A letter in the mail | _____ | _____ | _____ |
| j. Someone from the Study came to my door | _____ | _____ | _____ |
| k. Other | _____ | _____ | _____ |

**2. How did attending [*name of this activity*] affect your opinion about the National Children's Study?**

*Mark one box*

- ☐ [*The activity*] helped me feel more positive about the Study
- ☐ [*The activity*] did not change my opinion about the Study in any way
- ☐ [*The activity*] raised more questions or concerns about the Study

**3. How comfortable did you feel voicing your personal opinions at the NCS [*name of this activity*]?**

*Mark one box*

- ☐ Very comfortable
- ☐ Somewhat comfortable
- ☐ Neither comfortable or uncomfortable
- ☐ Somewhat uncomfortable
- ☐ Very comfortable

**4. Do you think you will attend another NCS Activity?**

- ☐ Yes
- ☐ No
- ☐ Maybe

**Thank you for taking the time to complete this questionnaire**.

Please put your completed questionnaire in the envelope provided and return the questionnaire to one of the NCS event staff. If you prefer, you also can return your completed questionnaire by mail using the postage-paid envelope.

# QUESTIONNIARE ADDRESSING:
# AWARENESS OF NCS
# (FOLLOWING THE PREGNANCY SCREENER)

(**Questions at the close of the pregnancy screener)**

**1. Before today, had you heard about the National Children's Study?**

☐ Yes
☐ No → *skip to the close of the pregnancy screener*

**2. How did you hear about the National Children's Study?** (check all that apply)

☐ Friends or acquaintances
☐ Family members
☐ Church, synagogue or other religious affiliation
☐ A community leader
☐ Someone else in the community (other than the NCS researchers)
☐ Doctor or health care provider
☐ Newspaper, T.V. or radio
☐ Billboard
☐ A letter in the mail
☐ Other → specify: _____

**3. Have you taken part in any local or community activities sponsored by the National Children Study, such as town meetings, community forums, community advisory boards, health fairs, or other activities?**

☐ Yes
☐ No → Continue to audio-casi.

**4. Would you describe the event as something like a health fair, a meeting with at least one speaker who presents information to an audience, a discussion group with a limited number of people participating, or something else?**

☐ A health fair (READ IF NECESSARY: for example, an event with informational booths or other health monitoring booths available for people to stop at as they choose),
☐ A meeting with at least one speaker who presents information to an audience,
☐ A discussion group with a limited number of people,
☐ Or something else → Please describe:
_____
_____

*-- CAPI continues with close of pregnancy screener module --*

# QUESTIONNIARE ADDRESSING: PARTICIPANT EVALUATION OF DATA COLLECTION ACTIVITIES

**NATIONAL CHILDREN'S STUDY**
**Participant Evaluation Questionnaire**

Thank you for participating in the National Children's Study (NCS). We would appreciate you taking a few minutes to answer some questions about your experience in the study so far. Your feedback will help us improve the National Children's Study for future phases of the study in which you or your child may choose to participate. Additionally, your feedback can help us improve this phase of the study for other women who haven't yet participated. Please answer these questions to the best of your ability.

Completion of this form is voluntary and you can choose to complete it or not. If you do not complete it, your participation in the National Children's Study (NCS) will not be affected. As with all other NCS activities, the information you provide will be kept confidential and used only for purposes of the study.

**1. Did a study representative conduct an interview with you?**

☐ Yes
☐ No → (GO TO 2)

**1a. How much time did you spend on the interview?**

☐ Far too much time
☐ A little too much time
☐ An acceptable amount of time

**1b. How uncomfortable or comfortable did you feel completing an interview with the study representative?**

☐ Very uncomfortable
☐ Somewhat uncomfortable
☐ Somewhat comfortable
☐ Comfortable

**1c. How clearly did a study representative explain the interview process to you?**

☐ Did not explain clearly at all
☐ Explained somewhat clearly
☐ Explain pretty clearly
☐ Explained very clearly

**2. Did a study representative collect environmental samples from your home, such as water, air, dust, or soil?**

☐ Yes
☐ No → (GO TO 3)

**2a. How much time did a study representative spend collecting environmental samples from your home?**

☐ Far too much time
☐ A little too much time
☐ An acceptable amount of time

**2b. How uncomfortable or comfortable did you feel with the study representative collecting environmental samples from your home?**

☐ Very uncomfortable
☐ Somewhat uncomfortable
☐ Somewhat comfortable
☐ Comfortable

**2c. How clearly did a study representative explain the process of collecting environmental samples to you?**

☐ Did not explain clearly at all
☐ Explained somewhat clearly
☐ Explain pretty clearly
☐ Explained very clearly

**3. Did you collect any environmental samples for the study, such as water, air, dust, or soil samples?**

☐ Yes
☐ No → (GO TO 4)

**3a. How much time did you spend collecting your own environmental samples for the study?**

☐ Far too much time
☐ A little too much time
☐ An acceptable amount of time

**3b. How uncomfortable or comfortable did you feel collecting your own environmental samples?**

- ☐ Very uncomfortable
- ☐ Somewhat uncomfortable
- ☐ Somewhat comfortable
- ☐ Comfortable

**3c. How clearly did a study representative explain the process of collecting your own environmental samples?**

- ☐ Did not explain clearly at all
- ☐ Explained somewhat clearly
- ☐ Explain pretty clearly
- ☐ Explained very clearly

**4. Did a study representative collect any biospecimens from you, such as blood, saliva, hair, or nail clippings?**

- ☐ Yes
- ☐ No → (GO TO 5)

**4a. How much time did a study representative spend collecting biospecimens?**

- ☐ Far too much time
- ☐ A little too much time
- ☐ An acceptable amount of time

**4b. How uncomfortable or comfortable did you feel allowing a study representative collect biospecimens?**

- ☐ Very uncomfortable
- ☐ Somewhat uncomfortable
- ☐ Somewhat comfortable
- ☐ Comfortable

**4c. How clearly did a study representative explain the process of collecting biospecimens to you?**

- ☐ Did not explain clearly at all
- ☐ Explained somewhat clearly
- ☐ Explain pretty clearly
- ☐ Explained very clearly

**5. Did you collect any of your own biospecimens for the study such as vaginal swabs or urine?**

☐ Yes
☐ No → (GO TO 4)

**5a. How much time did you spend collecting your own biospecimens for the study?**

☐ Far too much time
☐ A little too much time
☐ An acceptable amount of time

**5b. How uncomfortable or comfortable did you feel collecting your own biospecimens for the study?**

☐ Very uncomfortable
☐ Somewhat uncomfortable
☐ Somewhat comfortable
☐ Comfortable

**5c. How clearly did a study representative explain the process of collecting your own biospecimens to you?**

☐ Did not explain clearly at all
☐ Explained somewhat clearly
☐ Explain pretty clearly
☐ Explained very clearly

**6. Did a study representative collect any physical measures from you, such as blood pressure, weight, or height?**

☐ Yes
☐ No → (GO TO 7)

**6a. How much time did a study representative spend collecting physical measures from you?**

☐ Far too much time
☐ A little too much time
☐ An acceptable amount of time

**6b. How uncomfortable or comfortable did you feel having a study representative collect physical measures?**

- ☐ Very uncomfortable
- ☐ Somewhat uncomfortable
- ☐ Somewhat comfortable
- ☐ Comfortable

**6c. How clearly did a study representative explain the process of collecting physical measures to you?**

- ☐ Did not explain clearly at all
- ☐ Explained somewhat clearly
- ☐ Explain pretty clearly
- ☐ Explained very clearly

**7. Did you complete any paper questionnaires given to you by a study representative?**

- ☐ Yes
- ☐ No → (GO TO 8)

**7a. How much time did you spend on the paper questionnaires?**

- ☐ Far too much time
- ☐ A little too much time
- ☐ An acceptable amount of time

**7b. How uncomfortable or comfortable did you feel completing the paper questionnaires?**

- ☐ Very uncomfortable
- ☐ Somewhat uncomfortable
- ☐ Somewhat comfortable
- ☐ Comfortable

**7c. How clearly did a study representative explain the paper questionnaires to you?**

- ☐ Did not explain clearly at all
- ☐ Explained somewhat clearly
- ☐ Explain pretty clearly
- ☐ Explained very clearly

**T3X.** ***(T3 VERSION ONLY)*** **At a previous visit, the study representative may have left a diary with you to help keep track of things between visits such as any illnesses you experienced, injuries, or medicines that you may have used.**

**If you received a diary, <u>how difficult or easy was it to use the diary</u>?**

- ☐ Very difficult
- ☐ Somewhat difficult
- ☐ Somewhat easy
- ☐ Very easy
- ☐ I did not receive a diary

**8. How important were each of the following in your decision to participate in this phase of the National Children's Study?**

| | Not At All Important | Not Too Important | Somewhat Important | Very Important |
|---|---|---|---|---|
| a. Receiving payments or gifts for your participation? | _____ | _____ | _____ | _____ |
| b. Learning more about your health or the health of your child? | _____ | _____ | _____ | _____ |
| c. Helping your child as he/she develops? | _____ | _____ | _____ | _____ |
| d. Getting medical information about myself or my child that I wouldn't otherwise receive, including referrals to other doctors or specialists? | _____ | _____ | _____ | _____ |
| e. Feeling as if you can help children now and in the future? | _____ | _____ | _____ | _____ |
| f. Contributing to science? | _____ | _____ | _____ | _____ |
| g. To help the environment? | _____ | _____ | _____ | _____ |
| h. Feeling part of my community? | _____ | _____ | _____ | _____ |
| i. Knowing other people in the study? | _____ | _____ | _____ | _____ |
| j. Having family members or friends support your decision to participate in the study? | _____ | _____ | _____ | _____ |
| k. Having your doctor support your decision to participate? | _____ | _____ | _____ | _____ |
| l. Having a good relationship with the NCS researchers? | _____ | _____ | _____ | _____ |

**9. How much do each of the following people discourage or encourage your participation in the National Children's Study?**

| | Very Discouraging | Somewhat Discouraging | Neither Encouraging or Discouraging | Somewhat Encouraging | Very Encouraging |
|---|---|---|---|---|---|
| a. Family members | _____ | _____ | _____ | _____ | _____ |
| b. Friends | _____ | _____ | _____ | _____ | _____ |
| c. Your doctor or health care provider | _____ | _____ | _____ | _____ | _____ |

**T3Y. *(T3 VERSION ONLY)* How difficult or easy is it to schedule appointments for home or clinic visits?**

- ☐ Very difficult
- ☐ Somewhat difficult
- ☐ Somewhat easy
- ☐ Very easy

**T3Z. *(T3 VERSION ONLY)* How uncomfortable or comfortable are you at the NCS study center?**

- ☐ Very uncomfortable
- ☐ Somewhat uncomfortable
- ☐ Somewhat comfortable
- ☐ Very comfortable

**10. In general, how would you describe your experiences as a participant in the National Children's study?**

- ☐ Very negative
- ☐ Somewhat negative
- ☐ Neither negative or positive
- ☐ Somewhat positive
- ☐ Very positive

**11. Of all the study activities you participated in so far, which one did you like the most?**

_____

_____

_____

**12. Is there anything we can do to make your participation in NCS more enjoyable?**

_____

_____

_____

**13. In your opinion, how valuable do you think the National Children's Study will be to the health and well being of children?**

- ☐ Not at all valuable
- ☐ A little valuable
- ☐ Pretty valuable
- ☐ Very valuable

**Thank you for taking the time to complete this questionnaire**.

Please put your completed questionnaire in the envelope provided and return the questionnaire to the study representative before he or she leaves today. If the study representative leaves before you finish, or if you prefer, you also can return your completed questionnaire by mail using the postage-paid envelope.

## Healthcare Provider and Community Leader Evaluations

Healthcare Provider Evaluation:

The Pilot also will collect data from health care providers in order to understand whether a relationship exists between health care provider awareness and involvement in the NCS and overall enrollment in the NCS. The Healthcare Provider questionnaire is very brief, only 4 questions, and we estimate it taking any one provider less than a minute to complete. This evaluation data, coupled with information about the costs for outreach and promotion to healthcare providers (at a VC level) will be analyzed relative to enrollment rates. This information will inform outreach and promotion activities for the main Study.

To collect these data, each VC will develop a frame of healthcare providers in their area from which 650 providers will be sampled. The VCs will each assemble their own frame, including OB-GYN practices, prenatal clinics or other similar type health care providers that serve women expected to give birth at the hospitals or birthing centers in the VC area. To the extent possible, the frame will list by practice or clinic rather than individual provider to minimize the possibility that any one practice will have multiple providers selected to participate in this evaluation. In the event that a practice has multiple locations, each location will be listed separately on the frame.

Data will be collected primarily by mail, with an in-person follow-up for those sampled practices that do not respond by a certain date. The first contact will be a letter addressed to the Medical Director of XXXX Practice telling him or her about the purpose of the Study, why the Study needs their feedback and approximate date/week they will receive it in the mail. About 7 to 10 days after the advance letter, the VCs will send the single page questionnaire with a postage-paid return envelope to the same individual. A small value, non-monetary incentive will be included with the questionnaire. About a week after sending the questionnaire, the VCs will send a postcard to each sampled unit (but again addressed to the medical director) reminding them to take one minute to complete and return the questionnaire. If after 2 more weeks, the VC does not have a response from the sampled unit, study staff from the VC will visit the practice to collect the questionnaire. If the director (or his/her designee) has not completed the form, the interviewer will ask to complete it then.

Because each VC will implement this evaluation independently, they will monitor the data collection progress themselves. This will not be integrated into the IMS for the Pilot.

Community Leader Evaluation

Also as part of the Pilot, each VC will collect feedback from community leaders included in the outreach and promotion efforts within their VC for the purpose of understanding whether gaining support from these community leaders impacts overall enrollment rates in the VC. Specifically, the evaluation will focus on the level of awareness of the NCS reported by community leaders and their reported support for the NCS relative to enrollment rates. As with the Healthcare Provider evaluation, analysis of these data, and costs data, will inform outreach and promotion activities for the main study.

Each VC will identify the community leaders asked to complete the form. It's anticipated that outreach efforts within a VC will target specific community leaders or community groups. Thus, rather than sampling specific persons or groups from a larger list, only the specific leaders or community groups included in the outreach efforts will be asked to complete an evaluation form. The form itself is a single page asking only four questions. Given that the outreach and promotion activities include personal contacts with these individuals by design, study staff working on the outreach program at each VC will hand deliver the questionnaires to the community leader or groups. Since the questionnaire is so short, ideally the NCS staff person will complete the questionnaire with the target individual, but a postage paid return envelope also will be provided. Follow-up for non-responders will be by phone after the initial visit.

Since each VC will implement this evaluation independently, they will monitor the data collection progress themselves. This will not be integrated into the IMS for the Pilot.

**NATIONAL CHILDREN'S STUDY**
**Healthcare Provider Questionnaire *(Draft)***

Thank you for your interest in the National Children's Study (NCS). Please take a moment to answer a few questions about your experience with the study. Your feedback will help us improve the National Children's Study for future phases of the study. Please answer these questions to the best of your ability.

**1. How familiar are you with the National Children's Study?**

- ☐ Very familiar
- ☐ Somewhat familiar
- ☐ Not too familiar
- ☐ I have not heard of the National Children's Study

**2. In your opinion, how valuable do you think the National Children's Study will be to the health and well-being of children?**

- ☐ Not at all valuable
- ☐ A little valuable
- ☐ Pretty valuable
- ☐ Very valuable

**3. Have you taken steps to encourage any of your patients to enroll in the Study?**

- ☐ Yes
- ☐ No

**4. How much of a burden is it for you when a patient of yours enrolls in the National Children's Study?**

- ☐ Very burdensome
- ☐ Somewhat burdensome
- ☐ A little burdensome
- ☐ Not at all burdensome

**Thank you for taking the time to complete this questionnaire.**

Please put your completed questionnaire in the envelope provided and return the questionnaire to the study representative. If you prefer, you can also return your completed questionnaire by using the postage paid envelope.

# NATIONAL CHILDREN'S STUDY
## Community Leader Questionnaire

Thank you for your interest in the National Children's Study (NCS). Please take a moment to answer a few questions about your experience with the study. Your feedback will help us improve the National Children's Study for future phases of the study. Please answer these questions to the best of your ability.

**1. How familiar are you with the National Children's Study?**

- ☐ Very familiar
- ☐ Somewhat familiar
- ☐ Not too familiar
- ☐ I have not heard of the National Children's Study

**2. In your opinion, how valuable do you think the National Children's Study will be to the health and well being of children?**

- ☐ Not at all valuable
- ☐ A little valuable
- ☐ Pretty valuable
- ☐ Very valuable

**3. Have you taken steps to encourage community members to enroll in the Study?**

- ☐ Yes
- ☐ No

**4. Do you expect the National Children's Study to have a positive impact on your community?**

- ☐ Yes
- ☐ No

**Thank you for taking the time to complete this questionnaire.**

Please put your completed questionnaire in the envelope provided and return the questionnaire to the study representative. If you prefer, you also can return your completed questionnaire by using the postage-paid envelope.

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# Appendix C.10

# Day Care Centers Protocol

## CHILD CARE LOCATIONS SUBSTUDY APPROACH

The NCS approach to studying children's exposures during the time they spend in child care locations is through studying a statistically based subsample of the NCS births through what is called the Child Care Locations Substudy.

This document presents an overview of definitions and concepts needed for the substudy, which child care locations to include, sample design, and the general approach to assessing the child care environment. Two instruments to be used to determine quality characteristics of the child care location also are included.

### 1. Definitions and Concepts

A few key terms must be defined:

- *Child care* is defined as "care that occurs on a regular basis by someone other than the child's parents." *Regular* means that it occurs at least once per week.

- The *type of child care* refers to the person providing care as well as the location in which the care takes place. Child care is broadly defined as being either center-based or home-based. Center-based care and home-based care are mutually exclusive. *Center-based care* takes place in a child care center or facility. *Home-based care* is provided by a relative or a non-relative in a home, either the child's home, the provider's home, or another home. Because the NCS focuses on the environment and environmental exposures in the child's home, the Child Care Substudy is focusing on the environment and environmental exposures that occur outside the child's home. Child care type is further broken into what we are referring to as "locations" for this study. We use the term "locations" to refer to the location in which a child care arrangement occurs (e.g.., a center, the child's home, or someone else's home). This way of classifying child care arrangements is presented in Table 1.

A classification system that divides care into center-based or home-based, the relationship of the provider to the child, and the location where care takes place is consistent with other major studies including the Early Childhood Longitudinal Study, Birth Cohort (ECLS-B), the National Household Education Survey (NHES), the NICHD Study of Early Child Care and Youth Development (SECCYD), and the Survey of Income and Program Participation (SIPP).

**Table 1. Child Care Types and Locations**

| | Center-Based | Home-Based | | | |
|---|---|---|---|---|---|
| | Center | Non-relative | | Relative | |
| | | In Child's Home | Out of Child's Home | In Child's Home | Out of Child's Home |
| Environmental exposures | | | | | |
| Child care environment | | | | | |

*Note:* Gray shaded cells are excluded from the proposed Child Care Substudy because the environmental exposures in the child's home will be assessed as part of the core assessment. The cells filled with slanted lines are partially excluded from the Child Care Substudy. These providers will not be asked to participate in the child care provider telephone interview and no separate child care observation will be conducted. However, there will be an opportunity to collect some child care information from these providers if the mother names that person as the alternate caregiver to be interviewed in the core assessment. Regardless of whether an observational component is added to assess environmental influences, it will be important to ensure that questions for the alternate caregivers who are not fathers collect parallel information to that collected from caregivers in the Child Care Substudy. For example, it would be beneficial to collect information on proxies for child care quality, such as provider education and training and beliefs about caregiving.

- The NCS Child Care Substudy is tasked with assessing both environmental exposures in the child care setting and the child care environment itself. To help differentiate these two types of environmental factors, we will use the term *environmental exposures* to refer to assessments pertaining to measuring toxins in the environment. We will use the term *environmental influences* to refer to other characteristics of the study child's child care environment. The child care environment includes such influences as the quality and quantity of child care, the stability of child care, and other features of the child care environment that may affect a child's social, emotional, and cognitive development and health.

## 2. Which Child Care Locations Will Be the Focus of the Study

Because of the longitudinal nature of the study and the focus on child health exposures, the Substudy will be child-based with assessments occurring in the actual child care locations of study children.[1]

A child-based design will lead to assessments in the child care arrangements of study children. The Substudy will look at a census of locations used (at standard data collection points, currently 6 months and 12 months) by selected children. To implement this, a random subgroup of children would be placed into the Child Care Substudy at birth. Only those children in the Child Care Substudy would have their child care environment observed.[2] If the child currently uses a child care location for a sufficient duration of time (defined as a function of hours per week and months since

[1] We considered but rejected the possibility of selecting child care arrangements within a community where child care is provided rather than the actual care locations of study children. Under a locations-based study option, child care centers and/or home-based arrangements would be sampled and assessed. The location assessed would not necessarily (or likely) be a location where a study child is currently enrolled but rather would be sampled based on its being in the community where the child is located. Only locations which could be identified (e.g., licensed or otherwise listed) would be included. Some in-home child care locations are licensed, but many are not and thus would be excluded. In addition, it could be difficult to obtain lists of in-home licensed locations.

[2] It is important to note that only a percentage (roughly half) of children enrolled in the Child Care Substudy will be in regular child care at any point in their preschool years.

arrangement began), the location will be studied.[3] Assessments would take place in the actual child care arrangements of study children. All locations meeting the requirement for the minimum number of hours will be observed. A variety of criteria would be used to define further which arrangements would be studied.

The optimal strategy for understanding all of children's exposures is to assess a census of the locations ever attended by children selected for the Child Care Substudy. While it would be ideal to assess every child care arrangement that a child ever attends, from a practical and budgetary standpoint, the focus will be on arrangements that the child is currently attending at predetermined data collection points that mirror those in the main study.

## 3. Sample Design

Any location that a child selected for the Child Care Substudy has regularly used for child care would be eligible for the study, assuming it is a significant source of exposure. Exposure is a combination of the hours of use per week and number of weeks used. (Exposure also is a function of the environmental levels at the location but this is not known until after the sample of locations is selected.) We anticipate a two-tier eligibility rule: All locations used for child care by the child at the time of a regular core visit (e.g., 6 months and 12 months) used 30 hours will be studied, and a sample of 10 percent of those locations used 10 to 29 hours would be studied. In addition, all locations used 10 or more hours per week would be contacted by telephone to collect environmental influences information.

It is important to collect both environmental exposure and influences from the 10 percent sample of less-used locations since the conditions in heavily used locations might not accurately reflect the conditions in less-used locations. In addition, it is necessary to include data from less-used locations so that it is possible to minimize the effect of selection biases. Children are not randomly assigned to child care. There are geographic, socioeconomic, family, and child factors that effect dimensions of child care, such as the type of care selected and how much child care is used (age of entry and amount of care), that also affect child developmental and health outcomes. For example, family economic factors, maternal employment status, mothers' education, personality, and beliefs, and family size are associated with child care use (Hofferth et al., 1991; NICHD Early Child Care Research Network, 1997a). To make inferences about relations between child care and child outcomes, it is necessary to identify and control selection biases.

We anticipate including 20 percent of the pilot births (roughly 220 children) in the Substudy.

The plan is to use the results to impute child care influences and exposures for all 100,000 children in the NCS cohort. (This will allow child care influences and exposure data to be used when modeling outcomes for the entire cohort.) Parents of children not in the Substudy would also be asked questions about the extent and location of child care. This would be used to identify similar potential exposures among Substudy children.

---

[3] The minimum threshold for number of hours per week and length of time in the setting varies across major studies. For example, one criterion for an arrangement to be "observable" in the NICHD SECCYD is that the infant is in the arrangement for at least 10 hours per week. A criterion of 8 hours per week was used for preschoolers. For the ECLS-B, an interview with the child's primary child care provider was conducted for any child with a regular arrangement, and an observation of a child's child care arrangement was conducted for any child (sampled for the child care observation component) with a regular arrangement that occurred for at least 10 hours per week.

## 4. Measuring the Environment in the Child Care Setting

The first step in measuring the child care environment is identifying the environment of interest. To do this, the mother must first be asked questions about child care usage. The 6- and 12-month instruments will both have questions to allow the mother to report what arrangements the child has and provide permission for us to visit them.

Second, it is important to develop a plan that allows sufficient data to be collected to meet the multiple goals of this study.

**Environmental exposures**: The Child Care Locations Substudy will mirror exposure data collection at the 6-month home visit. A few measures of environmental exposures that are planned for the child's home may not be needed in a center setting. There is currently no plan to leave air monitors or other equipment in the child care location overnight. One additional test (fecal cultures from selected surfaces) has been proposed. Additional work is ongoing to see if any reductions can be made in the 6-month home protocol when it is applied to the Child Care Locations Substudy.

**Environmental influences:** The Child Care Locations Substudy will collect information on the characteristics of the child care environment in center- and home-based settings through a telephone interview with the child's non-parental child care provider. For example, information will be collected characteristics of the child care provider (e.g., education, training, knowledge of child development, and caregiver beliefs and attitudes), the caregiver-child relationship, the provider's assessment of the child's behavior and development, and other characteristics of the child care setting (e.g., other children in care, language spoken in the setting, etc.). This has been a standard approach used on such large studies as the ECLS-B, NHES, and the NICHD SECCYD. This data will be merged with data on the child's child care usage (e.g., quantity of care, stability of care) provided by all parents for analytic purposes.

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## NCS PROTOCOL SUMMARY OF ENVIRONMENTAL SAMPLES TO BE COLLECTED AT CHILD CARE LOCATIONS
## 9/11/2007

| **Dust** | Method | % Visits |
|---|---|---|
| Allergens, endotoxin (+ temp & RH) | Vacuum | 100 |
| Mold | Vacuum | 100 |
| Inorganics (wipe to be archived) | Wipe | 100 |
| SVOCs (wipe to be archived) | Wipe | 100 |
| Pesticides: Pyrethroids (composite, store 3 mos before analysis) | Wipe | 100 |
| TBD (vacuum dust to be archived) | Vacuum | 100 |
| **Drinking Water** | | |
| Disinfection Byproducts (DBPs) - HAA9 | Water | 1 per segment/ system/ year |
| Disinfection Byproducts (DBPs) - THMs | Water | 1 per segment/ system/ year |
| VOCs - non-community water source only | Water | 12 |
| Nitrate - non-community water source only | Water | 12 |
| **Soil** | | |
| Mid-yard soil (SVOCs - to be archived) | Soil | 100 (1 per structure) |
| **Visual Assessment - Building, Neighborhood - Indoor (and outdoor)** | | |

# Father's Role in Child Care

**Rationale:**

Fathers contribute to the development of their children in a variety of ways, most particularly emotional and economic support (Tamis-LeMonda and Cabrera 2002; Levine 1998; McBride, B., Rane, T.R., & Bae, J. 1999; Nord, C.W., Brinhall, D. & West, J. 1997). When it comes to child care arrangements, the father's role is primarily as a partner to the mother in making choices about the arrangement that will work best for the family, given the availability and quality of the child care available to the family. For example, local implementation and center supply conditions may be important factors affecting parents' child care selections (Fuller, Kagan, Caspary, & Gauthier, 2002). Additionally, knowledge about the father's role in the selection and scheduling of child care provides important information about the nature of the father's involvement and the level of stress and social support faced by the mother in negotiating work schedules and child care arrangements.

In the National Children's Study, the interview with the primary caregiver, typically the mother, asks a variety of questions about the nature of current and past child care arrangements that help to identify the types of arrangements (e.g., center-based vs. family child care vs. relative care), the amount of time the child spends in this care, and indicators of the quality of these care arrangements. It would be duplicative to ask the same questions of the father. On the other hand, there are many factors that are in play when parents decide on a suitable child care arrangement, and fathers may have different levels of involvement in these decisions. Additionally, fathers may have differential levels of involvement and participation in child care, from helping financially to taking the child to and from the child care, to stepping in to provide emergency support in case the child is ill or the child care is not available for a given day or period of time. The degree to which the fathers are involved financially, physically, and emotionally may affect the child's development by providing resources to the child's mother that may offset the stress of her parenting role.

**Hypotheses Involved:**

Domain of Exposure for hypotheses:

#13 Family Influences on Child Health and Development
#15 Impact of Neighborhood and Communities on Child Health
#16 Impact of Media Exposure on Child Health and Development
#17 Social Institutions and Child Health and Development

**Recommended Measure:**

**NICHD Early Child Care Study, My Child Questions (4 items).** All four items of these questions from the Study of Early Child are asked of the mothers and would then be asked of fathers if they have contact with the child care provider. These questions assess the father's perspective on the relationship

between his child and the child's caregiver. Items were answered according to Likert-type scales, with the scale points and anchors differing according to each question. As a result, the Cronbach's Alpha for the composite variable summing the scores across the four questions showed only moderate reliability (Cronbach's alpha's at 6 and 15 months were 0.580 and 0.619 respectively). Standardization of the items slightly improved the Cronbach's Alpha's and the Study of Early Child Care suggested omitting item 2 from the composite because it was poorly distributed at all assessment ages. Two additional questions were included to ask about procedures and plans if the respondent's child (or other children in care) is sick. The ability of the caregiver to isolate and remove sick children so as not to spread infection has been shown to be a good indicator of overall quality of the child care environment.

**NICHD Study of Early Child Care, Current Child Care Grid (Form 10A, 1 item)**. To identify the factors that fathers perceived as the reasons for the selection of the child care arrangement used most often, one item from this instrument was included. There is extensive literature on child care choices and the link between family resources, incomes, and education levels as well as the existing market conditions for the availability of different child care types on the choices parents make.

**Early Head Start National Evaluation, 14-Month Father Interview, Questions on father's responsibility in child care arrangements.** Three items taken from the EHS 14-month father interview determine the degree to which the father is involved in picking up or dropping off the child at the child care provider. One additional item asks about the sharing of costs for child care between the parents.

**Child Care Decision Making (Longitudinal Study of Australian Children).** In the father interview or self-administered questionnaire, we propose asking the same set of questions asked of the mother regarding the father's role in choosing a particular child care arrangement, from questions asked as part of the Longitudinal Study of Australian Children. Several items will ask the father about his role in choosing and organizing child care. Another item from the NICHD Study of Early Child Care was added asking for the different reasons why respondents chose the forms of child care that they were using.

**How Interview Component Will Be Conducted:**

SAQ, CAPI, or CATI

**Longitudinal Characteristics:**

6 months, 12 months, and 18 months

**Estimated Burden:**

Allocated per interview: 6 minutes
Estimated from Literature: N/A
Estimated from Pilot Test: To come

**Other Options Considered:**

None.

**Issues:**

Other questions already proposed for the father interview capture additional information regarding the father's provision of support to the mother regarding work schedules, financial and emotional support, including his contribution to child care.

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## Father's Involvement in Child Care Arrangements—Father SAQ Items

Next, I'd like to talk to you about different the experiences that {CHILD} has in child care from someone other than {{his/her} parents/you or {his/her} mother or guardians}. We are especially interested in how fathers think about these experiences and the role they may play. Child care includes regular child care and early childhood programs, whether or not there is a charge or fee, but not occasional babysitting.

Please answer these questions about the person or caregiver who overall spends the most time with {CHILD} on a weekly basis. If you are not sure how to answer a question, you can just say that you don't know.

### Section A. Father's Role in Parental Child Care Decision-Making[1]

A1. First, please tell me who is the person, other than you or your {spouse/partner/the child's mother} who provides the most amount of care for {CHILD} on a weekly basis. Is he/she a …

| | |
|---|---|
| Relative | 1 |
| Non-relative in a home | 2 |
| Child care center | 3 |
| Don't know | 8 (GO TO B1) |

Please answer the rest of these questions thinking only about this particular person who provides the most amount of care for {CHILD} on a weekly basis.

A2. Who chooses where your child goes for child care?

| | |
|---|---|
| Mother only | 1 |
| Mother mostly | 2 |
| Mother and father equally | 3 |
| Father mostly | 4 |
| Father only | 5 |
| Someone else (Specify _____) | 6 |
| Don't know | 8 |

A3. Who schedules and organizes the child care arrangements?

| | |
|---|---|
| Mother only | 1 |
| Mother mostly | 2 |
| Mother and father equally | 3 |
| Father mostly | 4 |
| Father only | 5 |
| Someone else (Specify _____) | 6 |
| Refused | 77 |
| Don't know | 88 |

[1] Source: Child Care Choices Study, Australia (A2, A3, A7), Early Head Start National Evaluation, 14 month Father Interview (A4-A6)

A4. Have you ever taken {CHILD} to child care or a child development center or picked up {CHILD} from there?

| | |
|---|---|
| Yes | 1 |
| No | 2 (GO TO A7) |
| Refused | 7 (GO TO A7) |
| Don't know | 8 (GO TO A7) |

A5. About how many times per month do you drop off or pick up {CHILD} from child care or a child development center?

Number of times per month: _____ OR

| | |
|---|---|
| Refused | 7 |
| Don't know | 8 |

A6. When you drop off or pick up {CHILD}, do you talk to the person who takes care of {CHILD}?

| | |
|---|---|
| Yes | 1 |
| No | 2 |
| Refused | 7 |
| Don't know | 8 |

A7. Who usually takes and picks up your child from child care?

| | |
|---|---|
| Mother only | 1 (GO TO C1) |
| Mother mostly | 2 (GO TO C1) |
| Mother and father equally | 3 (GO TO C1) |
| Father mostly | 4 |
| Father only | 5 |
| Someone else (Specify _____) | 6 (GO TO C1) |
| No one, child is cared for at home | 7 (GO TO C1) |
| Refused | 77 (GO TO C1) |
| Don't know | 88 (GO TO C1) |

*If father answer "father mostly" or "father only" in A5, go to Section B, otherwise go to Section C.*

**Section B. Respondent's Relationship with Child Care Provider[2]**

We'd like to find out a little bit about the relationship between your child's caregiver(s) and your child. For each of these statements, please select the best answer.

B1. Would you say that the relationship the caregiver(s) has with your child is

| | |
|---|---|
| Very close and loving -- like a member of the family | 1 |
| Positive, but not really close | 2 |

[2] Source: NICHD Study of Early Child Care, Form 15K, "My Child Care"

| | |
|---|---|
| Neither positive nor negative, but "businesslike" | 3 |
| Not positive at all | 4 |
| Refused | 7 |
| Don't know | 8 |

B2. When you pick up your child from the caregiver/center (or when you come after the child has been with the caregiver), does the child seem sad to leave the caregiver(s)?

| | |
|---|---|
| The child cries when he/she leaves the caregiver | 1 |
| The child looks sad when he/she leaves the caregiver | 2 |
| The child does not seem to mind when he/she leaves the caregiver | 3 |
| Refused | 7 |
| Don't know | 8 |

B3. When you drop the child off at the caregiver/center (or when the caregiver comes in the morning), does ***the child*** seem happy to see the caregiver(s)?

| | |
|---|---|
| Joyful—he/she lights up | 1 |
| Positive but not overjoyed | 2 |
| Doesn't seem to care one way or another | 3 |
| He/she is unhappy—looks sad | 4 |
| He/she is unhappy—sometimes even cries | 5 |
| Refused | 7 |
| Don't know | 8 |

B4. When you drop the child off at the caregiver/center (or when the caregiver comes in the morning), does ***the caregiver(s)*** seem happy to see the child?

| | |
|---|---|
| Joyful—the caregiver lights up | 1 |
| The caregiver is positive but not overjoyed | 2 |
| The caregiver doesn't seem to care one way or another | 3 |
| Refused | 7 |
| Don't know | 8 |

**Section C. Father's Role in Filling Emergency Child Care Needs[3]**

C1. In the last 2 months, has CHILD been sick on a day that your family relied on child care?

| | |
|---|---|
| Yes | 1 |
| No | 2 (GO TO D8) |
| Refused | 7 |
| Don't know | 8 |

C2. What did you or the child's mother do about child care the last time that happened?

| | |
|---|---|
| Child was in regular arrangement | 1 |
| Stayed or went home from work/school | 2 |
| Father/partner stayed or went home | 3 |
| Took child to work | 4 |

[3] Source: NICHD Study of Early Child Care, Form 15K, "My Child Care"

| | |
|---|---|
| Relative cared for child | 5 |
| Friend or neighbor cared for child | 6 |
| Hired sitter | 7 |
| Older child stayed with child | 8 |
| Used child care for sick children | 9 |
| Other (Specify):_____ | 10 |
| Refused | 77 |
| Don't know | 88 |

C3. What *usually* happens when your child (or one of the other child(ren) in care) is sick?

| | |
|---|---|
| The parent(s) has to make other arrangements if the child is at all sick. | 1 |
| The parent(s) has to make other arrangements only if the child is very sick | 2 |
| The caregiver takes the child, but keeps him/her isolated from other children (or there are no other children). | 3 |
| The caregiver makes other arrangements for the child (has someone else take care of him/her, etc. | 4 |
| Other (Specify _____) | 5 |
| Refused | 7 |
| Don't know | 8 |

C4. Who *usually* cares for your child when he/she is sick and cannot attend child care?

| | |
|---|---|
| Mother only | 1 |
| Mother mostly | 2 |
| Mother and father equally | 3 |
| Father mostly | 4 |
| Father only | 5 |
| Someone else (Specify _____) | 6 |
| Refused | 77 |
| Don't know | 88 |

C5. For the child care arrangement that you use the most, what factors influenced your and your (spouse/partner)'s decision to use this particular arrangement? (MARK ALL THAT APPLY).[4]

| | |
|---|---|
| Cost | 1 |
| Convenient hours | 2 |
| Convenient location | 3 |
| Quality of care provided | 4 |
| Quality environment/equipment | 5 |
| Quality of program | 6 |
| Preference for relative provider | 7 |
| Preference for home environment | 8 |
| Preference for center environment | 9 |
| Availability | 10 |

[4] Source: NICHD Study of Early Child Care, Form 10A "Current Child Care Grid"

| | |
|---|---|
| Other (Specify _____ _____) ..... | 11 |
| Refused ..... | 77 |
| Don't know ..... | 88 |

C6. How do you and {CHILD'S MOTHER} share the costs of child care or the child development center?[5]

| | |
|---|---|
| Do you share 50/50 ..... | 1 |
| Do you pay most, or ..... | 2 |
| Does she pay most ..... | 3 |
| Refused ..... | 7 |
| Don't know ..... | 8 |

[5] Source: Early Head Start Research and Evaluation Project, Two-Year Father Interview, "Child Related Services" (A4-A6), "Child Support and Paternity" (C6)

## Child Care Substudy Provider Interview

The Berkeley–Yale interviews for child care providers are telephone or in-person interviews designed to capture the quality of the child care setting. These interviews cover physical features of the child care setting, activities done in the setting, interpersonal interactions in the setting, and the relationship between the provider and parents. Additionally, provider education and experience are included in the questions. These questionnaires were designed to be used as an alternative to more burdensome observations of the child care setting by a trained professional.

**Administration Time:**

20–30 minutes

**Administration Method:**

Interview of child care provider can be administered either in person or by phone. Plan is to administer by phone at time of scheduling for environmental appointment.

**Administration Procedures:**

The interview is conducted with the child care provider and asks about the child care setting and provider rather than about the child. There are two alternate forms, one for Child Care Centers and the other for Family Day Care Homes. Only one of the two forms is administered to a provider. The choice of form is determined by the type of child care setting.

***Child Care Centers***

This 22-item questionnaire covers a variety of aspects of quality of the child care center setting, including space and furnishings, personal care routines, language-reasoning experiences, activities, interpersonal interactions (staff–child and child–child) in the care setting, and parent relations and services. Questions pertaining to caregiver background and training also are asked.

***Family Day Care Homes***

This 29–item questionnaire covers a variety of aspects of quality of limited-resource child care settings, including space and furnishings, basic care routines, language-reasoning experiences, learning activities, and parent–staff relations and services. Questions pertaining to the provider's amount of experience in the child-care field, education level, membership in a professional caregiver organization, and opportunities to attend child-care related training or conferences also are addressed.

## Berkeley–Yale Telephone Interview for Child Care Centers (BYTI-C)

### Introduction

Hello, my name is _____ and I am calling from _____. [Fill in particulars here regarding how they were selected]. I'd like to talk with you about your child-care classroom. Our conversation should take about 20 to 30 minutes. Is this a convenient time for you to talk?

(If YES: Great! Can we begin now?).
(If NO: I'd be happy to call back at a more convenient time if that would make a difference to you.)
(If still NO: Thank you for your time.)

We know how challenging it can be a child-care teacher, given limited resources, space, and time. In order for us to get an accurate picture, we ask that you listen carefully to each question and respond with the answer that you feel best characterizes your classroom.

For the sake of time, it would be helpful if, as I read the questions, you respond with letter—a, b, c, or d—of the response that best describes your classroom. At the end of the survey you will have a chance to say more about particular questions I asked, if you choose.

Your responses are completely confidential and we will assign you an identification number rather than use your name. Do you have any other questions before we begin?

### Program Size

1. On a typical morning, that is, between 9 am and noon, how many children are present in your classroom? _____ children

2. On a typical morning, including yourself, how many people work with you in the classroom? By this, I mean people who are teachers or aides. _____ workers

### Space & Furnishings

3. Different programs organize their space in different ways, especially as far as dividing rooms into separate learning centers. Which of the following best describes your room?

a. There is not enough space or materials to establish separate learning centers.
b. There are at least 2 learning centers, but they are not separated from the rest of the room.
c. There are at least 3 learning centers that are separated from the rest of the room and are well-equipped.
d. There are at least 5 well-equipped learning centers providing a variety of learning experiences. Children are able to help themselves to what they need.

## Language-Reasoning Experiences

4. Sometimes budgets don't allow child-care providers to purchase all the toys and materials they would like. The next question refers specifically to the amount of educational materials relating to language development, including books as well as music tapes and picture card games. Which best describes your classroom?

a. There are few books in the classroom.
b. Children have enough books to avoid conflict, if several want to use them during free play.
c. There is a wide selection of books available for a substantial portion of the day. Some additional language materials are used daily.
d. The classroom has a large variety of materials in good condition present for free choice and supervised use. There are enough materials of sufficient variety that the teacher can rotate them every few weeks.

5. Now I am interested in communication activities such as talking about drawings, sharing ideas at circle time, singing songs. Which of the following best fits your classroom?

a. There is rarely time for communication activities.
b. There are 1 or 2 communication activities a week.
c. Communication activities take place daily during both free play and group times.
d. The staff designs daily communication activities for free play and group time. Some of the activities link children's spoken communication with written language, for example, a teacher writes down a story as the children dictate.

## Activities

6. When it comes to materials involving fine motor skills and hand–eye coordination, such as pegboards and puzzles, which best describes your class?

a. Few materials are present in the classroom. Some materials are missing pieces or are damaged.
b. The classroom has some materials that are in fair to good condition, although the classroom could use a wider variety of materials.
c. The classroom has many materials in good condition. Materials are on different levels of difficulty.
d. There are enough good materials that you can rotate them every few weeks.

7. When it comes to art activities and materials, which best describes your setting?

a. There are few art materials available every day for the children.
b. There are some art materials, including those where children are able to express themselves in their own way.
c. There are many, varied art materials accessible by the children. There is much individual expression in the use of these materials.
d. In addition to option c, there are three-dimensional art materials such as clay. Some of the art activities are related to other classroom experiences, such as painting with fall colors when learning about the seasons.

8. Centers vary greatly on the amount of space and resources available to provide sand and water play.

8a. Do you have provisions for sand play (or a similar material like rice) indoors?

a. Yes
b. No

8b. What about sand play outdoors?

a. Yes
b. No

8c. What about water play indoors?

a. Yes
b. No

8d. What about water play outdoors?

a. Yes
b. No

9. I am interested in the materials available for dress-up or dramatic play activities. Which best describes your classroom?

a. There are no special materials available for dramatic play.
b. There are some props available for dramatic play, mostly to play house.
c. There is a variety of dramatic play props and they involve at least two themes. For example, house keeping and work.
d. Dramatic play materials are rotated occasionally to provide a complete change of themes. Pictures, stories and trips are used to enrich dramatic play.

10. Do the children have access to a television?

a. Yes
b. No

11. Do the children have access to a VCR?

a. Yes
b. No

12. When it comes to the amount that children are supervised as they play with gross motor equipment such as tricycles, which best describes your classroom?

a. There is not always enough staff to watch children as they play with gross motor equipment.
b. The children are supervised by staff to avoid accidents. Otherwise, children are encouraged to play on their own.
c. Children using gross motor equipment are given help when they ask for it.
d. Staff talk with children as they play, asking them to talk about what they are doing. Staff provide additional resources and guide children in their play.

13. For how much of the day are the children doing an activity as a whole group—such as listening to a tape or doing the same art project?

a. Most of the day
b. 50–75% of the day
c. 25–50% of the day
d. Less than 25% of the day

14. How often do the children in your class use work sheets to learn a skill? By this we mean exercises to learn their ABCs or practice numbers, not drawing or art.

a. Every day
b. A few times a week
c. A few times a month
d. A few times a year or never.

**Interaction**

15. Which of the following best describes your classroom as far as the amount and type of interaction between staff and children?

a. Due to their many responsibilities, some staff members are sometimes too busy to respond immediately when a child wants their attention.
b. The staff usually have the time to respond to children who ask for attention, but they sometimes feel hurried.
c. The staff have ample time to listen to each child who wants attention.

16. As far as children's interactions with each other, which best characterizes your classroom?

a. The children often seem to be by themselves or get into conflicts when they try to play with peers.
b. The children's interactions with peers are usually positive. They usually play well together without fighting.
c. The children seem to have formed strong emotional connections with each other. They play together and are usually able to resolve differences of opinion.

**Parents and Staff**

17. How much time were you able to spend during the last 12 months at child-related training programs, workshops, or conferences?

a. Less than 5 hours
b. 5 to 10 hours
c. 11 to 20 hours
d. More than 20 hours

18. Are you a member of a formal group or association of people who work with young children?

a. Yes
b. No

19. Some centers have the resources to provide for professional materials, workshops, courses, and/or in-service training. Which of the following best describes your center?

a. The center doesn't have the resources to provide professional materials or in-service training.
b. There is some in-service training for staff and occasional staff meetings.
c. Monthly staff meetings are used to handle administrative concerns and include staff development activities. Books and magazines about child care are available on-site.
d. Financial support is available for staff to attend conferences or workshops and to purchase materials.

20. Are staff with less than an AA degree in early childhood education required to continue formal education?

a. Yes
b. No

21. How long have you worked as a teacher or aide in the child-care field? _____ years

22. What is your highest level of education? Stop me when I get to the one that applies to you.

a. Less than high school
b. GED, high school diploma, or CDA credential
c. Some college
d. 2-year/associate's degree
e. 4-year/bachelor's degree
f. Master's degree

Is there anything you'd like to add about any of the questions I've asked? Thank you very much for your help.

## Berkeley–Yale Telephone Interview for Family Child-Care Homes (BYTI-F)

### Introduction

Hello, my name is _____ and I am calling from _____. [Fill in particulars here regarding how they were selected]. I'd like to talk with you about your family child-care home. Our conversation should take about 20 to 30 minutes. Is this a convenient time for you to talk?

(If YES: Great! Can we begin now?).
(If NO: I'd be happy to call back at a more convenient time if that would make a difference to you.)
(If still NO: Thank you for your time.)

We know how challenging it can be to run a child-care setting given limited resources, space, and time. In order for us to get an accurate picture, we ask that you listen carefully to each question and respond with the answer that best characterizes your setting.

For the sake of time, it would be helpful if, as I read the questions, you respond with the letter—a, b, c, or d—of the response that best describes your family child-care home. At the end of the survey you will have a chance to say more about particular questions I asked, if you choose.

Your responses are completely confidential and we will assign you an identification number rather than use your name. Do you have any questions before we begin?

### Program Size

1. On a typical morning, that is, between 9 am and noon, how many children are present in your setting? _____ children

2. On a typical morning, including yourself, how many people work with you in your setting? _____ workers

## Space & Furnishings

3. Family child-care settings vary as to the amount of space they have available to post child-related pictures and art work. Which describes your child-care setting?

a. There is no space available to display child-related pictures, mobiles, or children's art work.
b. There is some children's art work displayed and you have some store-bought or adult-made pictures for children to look at.
c. There is much children's work displayed, at least two items per child enrolled. Some of it is down low at the child's eye level.
d. There are many items of interest to children displayed where the children can see them. The display is changed at least monthly to match the children's activities and interests.

4. Do you have any areas in your setting that are specifically set up just for one type of play, like a block area or a dress-up area?

a. Yes
b. No

5. Which best describes how you prevent children from breaking fragile objects like flower vases?

a. You teach children not to touch them.
b. You remove them from the areas used by children.

6. How satisfied are you with the amount of space you have for children?

a. Somewhat satisfied
b. Moderately satisfied
c. Very satisfied

7. We are interested in learning about the availability of items for active play, for example, tricycles. Which best describes your child-care setting?

a. Little active play equipment is available at this time.
b. You have some equipment in good condition, but there is not a lot of variety.
c. The room has a wide variety of equipment in good condition.
d. The room has many different kinds of equipment in good condition. The equipment stimulates skills on different levels. For example, tricycles with and without pedals.

**Basic Care Routines**

8. We're interested in how things go when children arrive in the morning. Which of the following is most like your child-care setting?
   a. You are often too busy to greet children individually.
   b. Most of the children and parents will be greeted as they arrive. With so many families coming and going, however, some children may arrive without being greeted.
   c. You greet each child and parent upon arrival.
   d. You have a conversation with each child and parent upon arrival. You also use this time to talk informally with the parents or to help a child become involved in an activity.

9. How often do you have a chance to sit with the children while they are eating?
   a. Never
   b. Sometimes
   c. Often
   d. Always

**Language-Reasoning Experiences**

10. Sometimes budgets don't allow child-care providers to purchase all the toys and materials they would like. The next question refers specifically to the amount of educational materials relating to language development, including books as well as music tapes and picture card games. Which best describes your program?
   a. There are fewer than 6 children's books and no other materials available.
   b. There are at least 10 children's books and some other materials that you use at least 3 times a week.
   c. There are at least 20 children's books and various other materials for the children. You have at least one daily planned activity, such as reading or saying nursery rhymes.
   d. You check out materials from the library once a month or add to the material in other ways and use them in daily activities.

11. On an average day, how many minutes per day does someone read aloud to the children?
_____ minutes

12. How often do you ask children specific questions about the story when you read aloud?
   a. Every day
   b. Most of the time
   c. Sometimes
   d. Rarely

13. Which best represents the type of informal conversation that takes place in your setting?
    a. You talk with the children primarily while managing routines like toileting, or to correct a child's behavior.
    b. You have time for short, social conversations with most of the children.
    c. You have many conversations with children and try to make comments that build on ideas presented by them.
    d. You make sure to have a conversation with each child every day and often ask questions to encourage them to talk more.

**Learning Activities**

14. When it comes to materials involving hand–eye coordination, such as pegboards and puzzles, which best describes your setting?
    a. At this time, I have no hand–eye coordination materials.
    b. There are some hand–eye materials available for children to use independently.
    c. There is a variety of hand–eye materials as well as space to play with the materials.
    d. I have a wide range of materials that are rotated to maintain interest. They also are organized and labeled to encourage self-help.

15. When it comes to art activities and materials, which best describes your setting?
    a. There are no art materials available for use by children.
    b. There are some materials, including drawing, at least twice a week.
    c. There are crayons and paper, or other drawing materials available daily. Art materials needing supervision are planned at least 3 times a week, such as cutting and pasting, or painting.
    d. There are at least 2 different activities offered daily. Activities include at least one 3-dimensional material per week, such as clay or carpentry.

16. Family child-care homes vary greatly on the amount of space and resources available to provide sand and water play.

16a. Do you have provisions for sand play (or a similar material like rice) indoors?
    a. Yes
    b. No

16b. What about sand play outdoors?
    a. Yes
    b. No

16c. What about water play indoors?
    a. Yes
    b. No

16d. What about water play outdoors?

a. Yes
b. No

17. I am interested in the resources available for dress-up or dramatic play activities. Which best describes your child-care setting?

a. There are not special materials available for dramatic play.
b. There are some props available for dramatic play, mostly to play house.
c. There is a variety of dramatic play props and they involve at least two themes. For example, house keeping and work.
d. There is a variety of props involving two themes. The props are arranged in their own space and include child-sized play furniture, like a small stove or a baby stroller.

18. How often do the children have access to the computer?

a. Every day
b. A few times a week
c. A few times a month
d. A few times a year or never

19. How often do they have access to the television or videos?

a. Every day
b. A few times a week
c. A few times a month
d. A few times a year or never

20. How often do you talk with the children about what they are watching on the television or VCR?

a. Always
b. Often
c. Sometimes
d. Rarely or never

21. How often do the children in your setting use work sheets to learn a skill? By this we mean exercises to learn their ABCs or practice numbers, not drawing or art.

a. Every day
b. A few times a week
c. A few times a month
d. A few times a year or never.

## Parents and Staff

24. Do you have a regularly scheduled parent conference?
    a. Yes
    b. No

25. I am interested in knowing how you are able to balance personal and caregiving responsibilities. Which description best describes you?
    a. Many housekeeping duties and family errands come up throughout the day.
    b. You make some changes in your own schedule of housekeeping and family errands on a day-to-day basis to meet caregiving responsibilities.
    c. You make plans so that family responsibilities and caregiving seldom interfere with one another. You have a substitute available as an emergency back-up.

26. Some providers have the opportunity to attend child-related training, workshops, or conferences. How much time did you spend during the last 12 months at child-related training programs, workshops, or conferences?
    a. Less than 5 hours
    b. 5 to 10 hours
    c. 11 to 20 hours
    d. More than 20 hours

27. Are you a member of a formal group or association of people who work with young children?
    a. Yes
    b. No

28. We would like to find out a little bit about you and your job. How long have you worked as a provider in the child care field? _____ years

29. What is your highest level of education? Stop me when I get to the one that applies to you.
    a. Less than high school
    b. GED, high school diploma, or CDA credential
    c. Some college
    d. 2-year/associate's degree
    e. 4-year/bachelor's degree
    f. Master's degree

Is there anything else you'd like at add about the questions I've asked you?
Thank you very much for your help.

# Appendix C.11

# Reports of Findings and Referrals

# APPENDIX X: REPORT OF FINDINGS AND REFERRALS

## 1. Overview

Participants in the National Children's Study (NCS) will receive notification of the results of some of the exams and tests that they participate in as part of the Study. The method and time frame for communicating the results to participants will depend on the medical findings and the time required for processing the results. In instances where the exam results are immediately available (e.g., blood pressure), the participant will receive the results at the end of their exam, in a Preliminary Report of Findings printed on a hard copy form. Some reportable results will not be processed immediately but will be sent to participants 8–12 weeks following the exam in a Final Report of Findings.

In instances where exam results indicate further medical attention, participants also will receive a referral letter with information about the results and a recommendation regarding the time frame when they should contact their health care provider about these results. Referrals will be distributed during home or clinic visits for immediately available test results or via the mail and/or the Internet for biospecimen results.

## 2. Preliminary Report of Findings

Participants will receive a Preliminary Report of Findings after completing a physical exam, either at home or at a clinic. The findings for those exam results that are immediately available (e.g., blood pressure) will be written on a hard copy form. In addition to exam results, the Preliminary Report of Findings also will include an interpretation of the results based on predetermined criteria. The interpretation will, in most cases, be different for adults and children.

The Visit Coordinator will be responsible both for giving the participant the Preliminary Report of Findings and verbally reviewing the results with the participant. The form will list an 800 number for the participant to call should they have follow-up questions about the tests or results.

The tests and measures that will be reported in the Preliminary Report of Findings include blood pressure, heart rate, weight, height, and body mass index. A brief description of the criteria and statements for these reported measures is outlined below.

**Blood Pressure (adults):** Systolic and diastolic blood pressure are categorized into specific ranges and assigned a statement indicating whether the results are within the normal range or in one of several ranges above the normal range. See Table 1 for Report of Findings statements for adults 18 years and above. The cells specify the blood pressure category (1–5) for the systolic and diastolic blood pressure combination. The category number defines the statement used for the report of findings. If the results are above the normal range, the participant will also receive a referral letter to give to their physician (See Section 4 for referral procedures).

Table 1. Statement by result category for blood pressure report of findings (adults $18^{+}$) [1]

| Category | Systolic | Diastolic | Report of Findings Statement: *"Your blood pressure today is…"* |
|---|---|---|---|
| 1 | <120 | <80 | …within the normal range. [11] |
| 2 | 120-139 | 80-89 | …above normal and is in the pre-hypertensive range. [1] |
| 3 | 140-159 | 90-99 | …high. [1] |
| 4 | 160-209 | 100-119 | …very high. [1] |
| 5 | >209 | >119 | …severely high. |

**Blood Pressure (children):** Children's normal blood pressures vary by age, weight, and height. The tables for children's blood pressures are taken from the National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents.[2] The tables provide matrices of combinations of systolic and diastolic blood pressure results by percentile of height for males and females ages 6 through 17 years. The matrix cells specify the blood pressure category (1–4) for the systolic and diastolic blood pressure combination. The category number defines the statement used for the report of findings. See Table 2. If the results are above the normal range, the participant will also receive a referral letter to give to their physician (See Section 4 for referral procedures).

[1] Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003

[2] National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report from the National High Blood Pressure Education Program. *Pediatrics*. 1996; 11:649–658.

Table 2. Statements by result category for blood pressure report of findings (children)[2]

| Category | Report of findings statement<br>*"You child's blood pressure today …"* |
|---|---|
| **1** | …is within the normal range.* |
| **2** | …is normal but at the high end of normal range.* |
| **3** | …high.* |
| **4** | … very high.* |

**Weight, height and body mass index:** Children less than 3 years of age will be given results for weight and recumbent length. Body mass index will not be calculated for this age group. Although measurements are recorded in metric units for data collection purposes, the results for the Report of Findings will be converted to English units.

Weight and height measurements along with the calculated body mass index (BMI) from each visit will be given to participants ages 20 years and above at the end of the visit. These measurements along with a brief statement about the significance of the results will be printed on the hard copy report. The technician will check the appropriate statement based on the body mass index percentile. The statements for this age group associated with each body mass index category are displayed in Table 3.

Table 3. Statements by BMI categories for report of findings (≥20 years).

| Body Mass Index | Report of Findings Statement for weight status based on BMI:<br>*"Body mass index (BMI), a number calculated from a person's weight and height, is a measure of body fatness. Although it does not measure fat directly, research has shown that BMI is related to direct measures of body fat. Your weight status category can be determined from the table below:"* |
|---|---|
| Below 18.5 | Underweight. |
| 18.5–24.9 | Normal |
| 25.0–29.9 | Overweight |
| 30 and above | Obese |

Exhibit 1. Sample Preliminary Report of Findings hard copy form (<20 years)

*{NCS Letterhead}*

**National Children's Study**
**PRELIMINARY REPORT OF FINDINGS†**

Date of Examination: __ __ /__ __ /20 __ __

Participant Name: _____

**BODY MEASUREMENTS**

Height: __ feet __ __ inches

Weight: __ __ __ pounds

Body Mass Index (BMI): __ __ .__

Body mass index (BMI), a number calculated from a person's weight and height, is a measure of body fatness. Although it does not measure fat directly, research has shown that BMI is related to direct measures of body fat. Your weight status category based on your body mass index can be determined from the table below:

| **Body Mass Index** | **Weight Status** |
|---|---|
| Below 18.5 | Underweight |
| 18.5–24.9 | Normal |
| 25.0–29.9 | Overweight |
| 30 & above | Obese |

**BLOOD PRESSURE AND HEART RATE**

Systolic Blood Pressure: __ __ __ mmHg

Diastolic Blood Pressure: __ __ __ mmHg

Resting Heart Rate: __ __ __ beats per minute

Your blood pressure today is*

___ within the normal range

___ above normal and is in the pre-hypertensive range

___ high

___ very high

___ severely high

*Categories are based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.

† The purpose of the study examinations is data collection, not diagnosis or treatment. The study examinations are not intended to substitute for a clinical exam. Adults should see their doctor once a year for an annual exam.

**Ultrasound image:** Participants will be given an image from each of the ultrasounds performed as part of the study.

A sample Preliminary Report of Findings for participants 20 years and above is displayed in Exhibit 1.

### 3. Final Report of Findings

The Final Report of Findings will be generated electronically and will include all reportable exam results, regardless of referral level or the time it takes to process the results. The information provided in the Preliminary Report of Findings at the end of the exam visit will be repeated in the Final Report for the convenience of the participant. This includes blood pressure, heart rate, weight, height, body mass index and water-nitrates. Hemoglobin, hematocrit and water VOC will be included in the final report. An interpretation of the results will be included based on predetermined criteria.

The Visit Coordinator is responsible for ensuring that the Final Report of Findings is mailed to the respondent within 8–12 weeks of the examinations. The report will include an 800 number that the participant can call if there are any follow-up questions. An example of a Final Report of Findings is located in Exhibit 2a and 2b. The information that was provided in the Preliminary Report of Findings at the end of the exam visit will be repeated in the Final Report for the convenience of the participant.

Exhibit 2a. Sample Final Report of Findings (electronic)

*{NCS Letterhead}*
**National Children's Study**
**FINAL REPORT OF FINDINGS†**

Date of Examination: <Exam Date>

Participant Name: <Participant First and Last Name>

*(A copy of your blood pressure, heart rate, weight, and height results was given to you at the end of your visit. For your convenience, those results are listed again on this report.)*

**Laboratory**

Measured Hemoglobin: <Insert Measured Hemoglobin>

Measured Hematocrit <Insert Measured Hematocrit>

**Normal Values for Hemoglobin:**

| | |
|---|---|
| Adult Males: | 13.0–17.0 g/dL |
| Adult Females: | 12.0–15.0 g/dL |
| Infants, after neonatal period: | 11.0–14.0 g/dL |
| Children, 2 years to teenage: | Gradual increase to adult normals |

**Anthropometry**

Height: <Insert Height>

Weight: <Insert Weight>

Body Mass Index (BMI) <Insert BMI>

Body Mass Index (BMI), a number calculated from a person's weight and height, is a measure of body fatness. Although it does not measure fat directly, research has shown that BMI is related to direct measures of body fat. Your weight status category can be determined from the table below:

| **Body Mass Index** | **Weight Status** |
|---|---|
| Below 18.5 | Underweight |
| 18.5–24.9 | Normal |
| 25.0–29.9 | Overweight |
| 30 & above | Obese |

Exhibit 2b. Sample Final Report of Findings (page 2)

**National Children's Study Final Report of Findings†**
**Page 2**

**Blood Pressure and Heart Rate**

| | **Your Measurements** |
|---|---|
| Systolic Blood Pressure: | **<Insert Systolic BP>** |
| Diastolic Blood Pressure: | **<Insert Diastolic BP>** |
| Resting Pulse Rate: | **<Insert Pulse Rate>** |

Your blood pressure result is*

___ within the normal range
___ above normal and is in the pre-hypertensive range
___ high
___ very high
___ severely high

Your blood pressure today is based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.

† The purpose of the study examinations is data collection, not diagnosis or treatment. The study examinations are not intended to substitute for a clinical exam. Adults should see their doctor once a year for an annual exam.

**Environmental Samples**

Water VOCs <Insert Water VOC>

*{insert statement to explain the significance of the results}*

**4. Referrals**

Although the purpose of the NCS examinations is data collection, not diagnosis or treatment, physical exams and analysis of biospecimens and environmental samples may yield clinically significant findings that warrant further medical attention. In these situations, participants will receive same-visit notification of major medical findings for those exam results that are immediately available (e.g., blood pressure) and a referral letter will be issued to participants to give to their health care provider.

Exam results are classified into three referral levels. Referral letters will be given for results that fall in Level 1 and 2 categories.

Level 1: Major medical findings that warrant immediate attention by a health care provider.

Level 2: Major medical findings that require attention by a health care provider within the next two weeks because they are expected to cause adverse effects within this time frame.

Level 3: Normal medical findings or minor medical findings that an examinee already knows about, is under care for, or that does not require prompt attention by a medical provider.

**Immediate referrals (at the end of the exam):** The only exam result available at the end of the exam to establish the need for a referral is blood pressure. In the case of Level 1 findings, the Visit Coordinator will end the exam immediately and provide the respondent with a standard referral letter (Exhibit 3) in addition to a referral form with specific information regarding the results Exhibit 4 (for adults) and Exhibit 5 (for children). The Visit Coordinator will provide verbal instructions to see their health care provider immediately. If the examiner believes the participant is in imminent danger, he or she will also call 911 for medical assistance. In the case of Level 2 findings, the Visit Coordinator will be responsible for providing the respondent with a referral letter and specific form and instructions to see their primary care provider within 2 weeks. If the respondent does not have a primary care provider, the name and contact information for a doctor from the Study Center's health care provider referral list will be provided. This information will be written on the referral form. Level 3 findings are normal medical findings that do not require a referral.

**Later referrals (when tests are processed):** Referrals also will be issued for laboratory results that are processed after the exam (i.e., hemoglobin) indicating Level 1 or Level 2 findings. The Visit Coordinator will be responsible for calling participants and notifying them of Level 1 findings within two days of the test results being finalized. The Visit Coordinator will also be responsible for mailing and/or emailing a standard referral letter (Exhibit 3) and a specific referral form for Level 1 and Level 2 findings (Exhibit 6) within 2 days of the test results being finalized. This will inform the participant of the need to see a physician about the results and include an 800 number that they may call to contact the Visit Coordinator with further questions. Where the results pertain to environmental samples, the participant also will receive a pamphlet on the potential risks of the environmental exposure in addition to a referral letter (Exhibit 6). The Referral Form will list an 800 number where the doctor can reach the Visit Coordinator should they have any questions about the study. A Referral Information Form also will be included with each Referral.

Exhibit 3. Sample Standard Referral Letter for Physical Measures and Laboratory

{NSC Letterhead}

**National Children's Study**

**Referral Letter**

Participant's Name: _____

Physician's Name: _____

Address: _____

_____

_____

Date: __ __ /___ ___/ 20 ___ ___

Dear Doctor:

<Respondent Name> has voluntarily participated in the National Children's Study conducted by <Local Study Center> and the National Institute of Child Health and Development. The objectives of the National Children's Study are to obtain information on the health and development of U.S. children, including the health of their parents. As a result of the testing that was done, it was noted that on <Exam Date>, a finding was revealed that was outside the survey's medically acceptable range. This finding is described on the attached Referral Information Form page.

This examination is intended to collect health measures for research. It is not a complete physical exam. No attempt has been made to diagnose or treat medical conditions of the participants. The findings disclosed to you are done so with the participant's. The findings disclosed to you are done so with the participant's permission.

Should you have any questions, you may contact me at <Local Study Center>. The phone number is <Study Center 1-800 Phone Number>.

Cordially,

<Study Center Coordinator>
Study Center Coordinator
<Insert Local Study Center Name>

Exhibit 4. Referral Information Form for Blood Pressure (Adults $18^{+}$)

{NCS LETTERHEAD}

**National Children's Study**

**Referral Information Page for Blood Pressure (18 years and above)**

Blood pressure was measured in a seated position after resting quietly for several minutes. Three measurements were taken, the first measure was discarded and the average systolic and diastolic blood pressure was calculated from the remaining readings. The results are recorded below.

Systolic Blood Pressure: _____mm Hg
Diastolic Blood Pressure: _____mm Hg
Heart Rate: _____beats per minute

The participant's blood pressure is:
__ within the normal range*
__ above normal and in the prehypertensive range*
__ high*
__ very high*

It is highly recommended that your child see their physician:
___ immediately
___ within 2 weeks

Additional comments:

_____

_____

_____

* Categories are based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003

Exhibit 5. Referral Information Form for Blood Pressure (Child 6–17)

{NCS LETTERHEAD}

**National Children's Study**

**Referral Information Form for Blood Pressure (Child 6–17)**

Blood pressure was measured in a seated/supine position after resting quietly for several minutes. Three measurements were taken, the first measure was discarded and an average systolic and diastolic blood pressure was calculated from the remaining readings. The results are recorded below:

Systolic Blood Pressure; _____mm Hg

Diastolic Blood Pressure: _____mm Hg

Heart Rate: _____beats per minute

The participant's blood pressure is:

__ within the normal range*

__ normal but in the high end of normal*

__ high*

__ very high*

It is highly recommended that your child see their physician:

___ immediately

___ within 2 weeks

Additional comments:

_____

_____

_____

* Categories are based on the National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report from the National High Blood Pressure Education Program. *Pediatrics*. 1996; 11:649–658

Exhibit 6. Referral Information Form for Laboratory Results

{NCS LETTERHEAD}

**National Children's Study**

**Referral Information Form for Laboratory Results**

Measured Hemoglobin: <Insert Measured Hemoglobin>

Calculated Hematocrit <Insert Calculated Hematocrit>

**Normal Values for Hemoglobin:**

| | |
|---|---|
| Adult Males: | 13.0–17.0 g/dL |
| Adult Females: | 12.0–15.0 g/dL |
| Infants, after neonatal period: | 11.0 –14.0 g/dL |
| Children, 2 years to teenage: | Gradual increase to adult normals |

| **Action Limits for Hemoglobin*:** | **Low** | **High** |
|---|---|---|
| Male & female (<6years) | <6.5 g/dl | >14.5 g/dL |
| Female (>6years) | <6.5 g/dL | >16.0 g/dL |
| Male (>6.5 g/dL) | <6.5 g/dL | >18.0 g/dl |

It is recommended that <you/your child> see their physician within 2 weeks.

Additional comments:

_____

_____

_____

_____

_____

_____

_____

* Categories are based on data from the National Health and Nutrition Examination Survey (NHANES),

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# Appendix C.12

# IRB Certifications

**IRB Certifications**

# (To come)

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