Appendix C

Additional Study Documentation

Appendix C.1

Deleted

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

Appendix C.3

Summary of Data Collection Activities

NCS PROTOCOL OVERVIEW AND SUMMARY OF CONTACTS
July 31, 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 (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																										
Medical Care Log						M	M	→	→	→	→	→	→	→		C	→	→	→	→	→	→	→	→	→	→
Environmental																										
Indoor Air	M					*	*					M								X			X			
House Dust	M					M	M					M								X			X			
Drinking Water						M	M					M								X			X			
Soil																				X			X			
Visual Assessment	M					M	M					M								X			X			
Indoor Air (self-collected)													M[4]													X
House Dust (self-collected)													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			
Ultrasound								M[5]		M	M		M[6]													
Infant Neonatal Exam																C		C								
Infant Physical Exam																				C			C			
Lung Function																										
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)															C											
Urine (self-collected)	M	M[8]				M F	M F				M	M								C			C			
Hair	M					F	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						
Saliva (self-collected)								M			M	M									M F[9]			C		
Other																										
Medical Record - Ultrasound								M[5]																		
Chart Abstraction - Prenatal, Labor, and Delivery																M		M								
Chart Abstraction - Neonatal																C		C								
Community Based Food, Air, and Water Collection								M[10]	→	→	→	→	→	→	→	→	→	→	X[10]	→	→	→	→	→	→	→
Child Care Locations																						CC				CC
Neighborhood Assessment								M[10]	→	→	→	→	→	→	→	→	→	→	X[10]	→	→	→	→	→	→	→

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 collectior

[9] The saliva will be collected from the mother and the 2nd adult caregiver in the home (not necessarily the fathe

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

* T1 air samples will be collected in a sub-study of participant and wll include personal air monitoring.

NCS PROTOCOL OVERVIEW
SUMMARY OF QUESTIONNAIRE AND PSYCHOLOGICAL/DEVELOPMENTAL ASSESSMENTS
August 25, 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														
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			
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														
Racism/Discrimination																							M			
Life Events (self-administered)											M	M														
Parenting Stress																					M					
Work/Family Stress																								M		
Social Support						M	M					M								M						
Family Process																										
Quality of Relationships									M												F	M		M F		
Domestic Violence (acasi)						M	M				M	M												M		
Division of Labor																					M					
Health Behaviors (maternal)																										
Physical Activity	M																									
Maternal Sleep	M																			M						
Douching (acasi)						M	M																			
Caffeine Use	M					M	M																			
Tobacco Use (acasi)						M	M				M	M														
Environmental Tobacco Smoke Exposure (acasi)						M	M													M	F		M	F		
Alcohol Use (acasi)						M	M				M	M														
Binge Drinking (acasi)						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	
- Child 3-day Checklist (mailed self-administered questionnaire)																					M			M	M	
Media Exposure in Children																				M			M			
Mental Health & Cognition																										
Depression						M F	M F				M	M								M	F					
State Trait Anxiety																					M					
IQ						F	F																F			
Literacy																				M			F			
Maternal / Paternal Attachment																									M	

NCS PROTOCOL OVERVIEW
SUMMARY OF QUESTIONNAIRE AND PSYCHOLOGICAL/DEVELOPMENTAL ASSESSMENTS
August 25, 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		M	
Occupational/Hobby Exposures	M					M F	M F				M	M													M	
Take Home (Occupational) Exposures																					F		M	F		
Commuting						M	M																			
Product Use Questionnaire						M	M				M	M								M			M			M
Pets						M	M					M								M		M				M
Pesticide Use	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		M	M
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														
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																					M F		M	F		
Major life events																									M	
Child Language Development																							M			
Child Temperament / Emotional Regulation																					M				M	
Child Socio-Emotional Functioning / Behavior																							M			M
Child Autism Screening																									M	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.

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	44 mL (6 tubes)		52.5 mL (7 tubes)	52.5 mL (7 tubes)		60.5 mL (8 tubes)		33 mL (4 tubes)							
Spot Urine	40 mL		40 mL	40 mL		40 mL									
Pregnancy Urine **P1 study participants will be asked to collect a urine sample the morning after their positive pregnancy test.		40 mL													
Vaginal Swabs (3 swabs)	X		X	X		X									
Hair (~20 strands)	X					X									
Nails (clippings from all toes)						X									
Saliva (3 collections per day for 2 days)					X	X							X		
Cord Blood								X							
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 month 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		
Paternal															
Blood			27.5 mL (4 tubes)	27.5 mL (4 tubes)											
Urine			40	40											
Hair (~20 strands)			X	X											
Nails (clippings from all toes)			X	X											
2nd Adult Caregiver in Home															
Saliva (3 collections per day for 2 days)													X		
Child															
Heel Stick in conjunction with routine newborn heel stick collection (a 5 spot and a 2 spot blood 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	Hematocrit value to support potential future RBC folate measure	Stress hormones (e.g. cortisol, corticotropin releasing hormone, ACTH) Reproductive hormones (e.g. estriol, estradiol, progesterone) Infection and inflammation indicators (e.g. cytokines, interleukins, multiple Ig types) Glucose metabolism analytes (e.g. fasting blood glucose levels, insulin levels, HgbA1C) Nutritional analytes (e.g. RBC folate, vitamins, omega 3 fatty acids,) Metals (e.g. mercury, lead, cadmium) Non-persistent Pesticides (e.g. metabolites of atrazine, organophosphorus pesticides, and pyrethroid insecticides) Environmental phenols (e.g. bisphenol A and parabens) Persistent Organic Chemicals (e.g. dioxins and furans) 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 Illicit drug panel and cotinine Phytoestrogens Phthalates Perchlorate and iodide Stress hormone (cortisol) Infection indicators (PCR for Chlamydia/Gonnorhea) Metals (e.g. mercury, arsenic) Environmental phenols (e.g. bisphenol A) 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 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) Chemical contaminants (to be determined)
Cord Blood	Hematocrit value to support potential future RBC folate measure	Stress hormones (e.g. cortisol, corticotropin releasing hormone, ACTH) Reproductive hormones (e.g. estriol, estradiol, progesterone) Infection and inflammation indicators (e.g. cytokines, interleukins, multiple Ig types) Glucose metabolism analytes (e.g. fasting blood glucose levels, insulin levels, HgbA1C) Nutritional analytes (e.g. RBC folate, vitamins, omega 3 fatty acids,) Metals (e.g. mercury, arsenic) Non-persistent Pesticides (e.g. metabolites of atrazine, organophosphorus pesticides, and pyrethroid insecticides) Environmental phenols (e.g. bisphenol A and parabens) Persistent Organic Chemicals (e.g. dioxins and furans) Genetic Material to be collected (genomic and mitochondrial DNA, RNA, Peripheral blood mononuclear cells (PBMCs)
Meconium	None	Cotinine Organophosphate metabolites
Breast Milk	None	Nutritional analytes (e.g. antioxidants, lipids, carbohydrates, endogenous compounds) Phytoestrogens and other hormones Perchlorate, iodide, thiocynate, nitrate Metals (manganese and others) Non-persistent Pesticides (e.g. metabolites of atrazine, organophosphorus pesticides, and pyrethroid insecticides) Environmental phenols (e.g. bisphenol A and parabens) Persistent Organic Chemicals (e.g. dioxins and furans)

NCS PROTOCOL SUMMARY OF ENVIRONMENTAL SAMPLES BY CONTACT (FOR THE SAME HOME)

DRAFT -- 8/15/2008

			Pre- Pregnancy		Pregnancy						Birth	Post-natal		
			P1 Home	Within X days of P1	T1 - 1st (Home)	T1 - Prior (Home)	T3 - First (Home)	Days of T1, T1-Prior, T3-First	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	PU				X, PU	X, PU	
VOCs (Note: 10% subsample in pilot)	Badge	10 (pilot)	X	PU	**	**	X	PU				X, PU	X, PU	
Carbonyls (Aldehydes & Ketones)	Badge	100			**	**	X	PU	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% withou source)	Badge	50			**	**	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	X[5], return
Mold (to be archived)	Vacuum	100										X	X	
Inorganics/metals (wipe to be archived)	Wipe	100			X	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					X		
Pesticides: Pyrethroids (composite, store P1 wipes for 3 mos to determine pregnancy)	Wipe	100	X		X	X	X					X	X	X[5], return
Drinking Water														
Disinfection Byproducts (DBPs) - HAA9, THMs	Water	10%			X	X	X						X	
VOCs (pilot)	Water	12 (pilot) [2]			X	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	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.

** Substudy of air exposures including pesonal samples to be planned.

Community Outdoor Air - 9/17/07

Note: Each SC will likely be asked to submit a proposal for community outdoor air sampling, based on one 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)

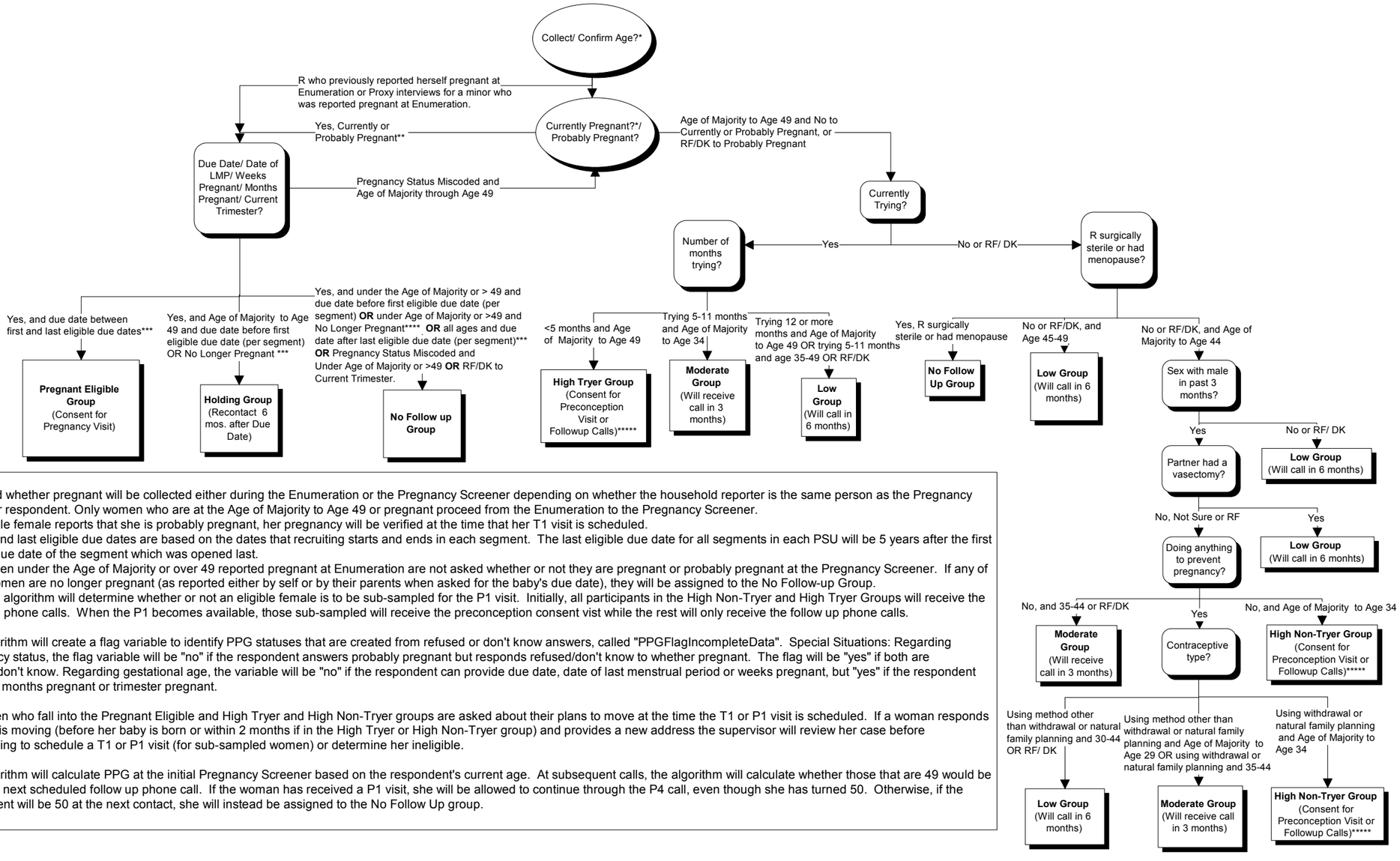
NCS Physical Measures Collections

Contact Schedule Physcial Measures 7-22-08	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																X	
Maternal Standing Height (2)											X																X	
Maternal Sitting Height (2)											X																X	
Maternal Mid Arm Circumference (2)	X					X	X				X																X	
Maternal Hip Circumference (2)	X																										X	
Maternal Waist Circumference (2)	X																										X	
Maternal Head Circumference (2)						X	X																				X	
Maternal Triceps Fold (2)	X					X	X				X																X	
Maternal Subscapular Skin Fold (2)	X					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)																											X	
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	
Infant/Child Abdomen Circumference (2)															X		X		X			X					X	
Infant/Child Thigh 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 (2)						X	X																					
Gestational age						X	X																					
Cardiac activity										X	X																	
Presentation										X	X																	
Biparietal Diameter (BPD) (2)										X	X																	
Head circumference (HC) (2)										X	X																	
Abdominal circumference (AC) (2)										X	X																	
Leg measured: (for FL, MTC, MTLC, MTA, MTLMA)										X	X																	
Femur length (FL) (2)										X	X																	
Mid thigh circumference (MTC) (2)										X	X																	
Mid thigh lean mass circumference (MTLMC) (2)										X	X																	
Mid thigh total area (MTA) (calculated)										X	X																	
Mid thigh lean mass area (MTLMA) (2)										X	X																	
Abdominal wall thickness (AWT) (2)										X	X																	
Sex										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																	

NCS Physical Measures Collections

Contact Schedule Physcial Measures 7-22-08																										
	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]**
Infant Neonatal Exam																												
2-D Images																X		X										
Face-frontal																X		X										
Face-profile (right)																X		X										
Face-profile (left)																X		X										
Anogenital Distance Measures																X		X										
Anterior penis to anus (AGD1) (2)																X		X										
Posterior base of penis to anus (AGD2) (2)																X		X										
Posterior of scrotum/fourchette to anus (AGD3) (2)																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										
Infant Physical Exam																												
2-D Face-frontal																				X			X				**X**	
2-D Face-profile right																				X			X					
2-D Face-profile left																				X			X					
																				X			X					

Initial Pregnancy Screener Algorithm 6.30.08



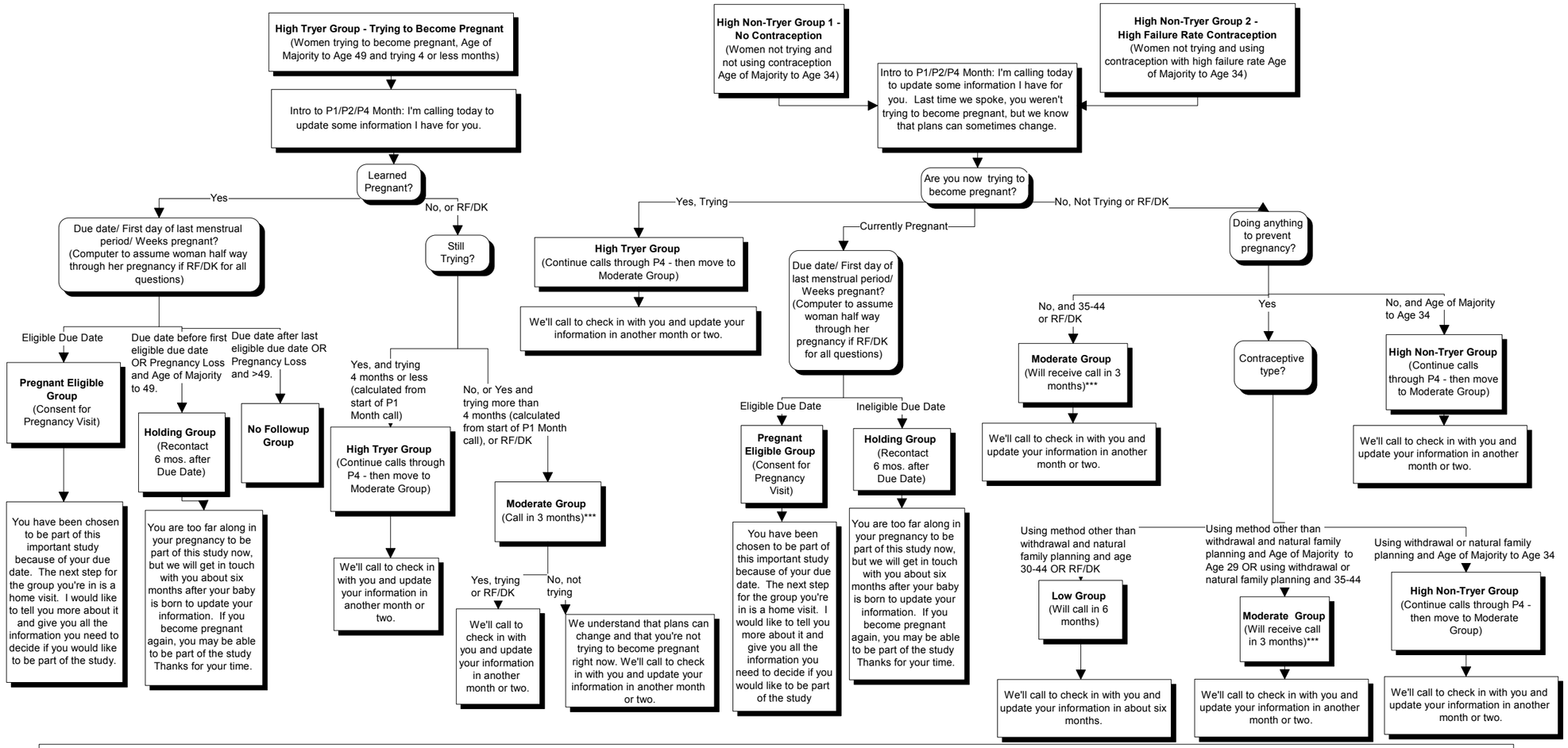
*Age and whether pregnant will be collected either during the Enumeration or the Pregnancy Screener depending on whether the household reporter is the same person as the Pregnancy Screener respondent. Only women who are at the Age of Majority to Age 49 or pregnant proceed from the Enumeration to the 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. The last eligible due date for all segments in each PSU will be 5 years after the first eligible due date of the segment which was opened last.
****Women under the Age of Majority 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.
***** The algorithm will determine whether or not an eligible female is to be sub-sampled for the P1 visit. Initially, all participants in the High Non-Tryer and High Tryer Groups will receive the follow up phone calls. When the P1 becomes available, those sub-sampled will receive the preconception consent vist while the rest will only receive the follow up phone calls.

The algorithm will create a flag variable to identify PPG statuses that are created from refused or don't know answers, called "PPGFlagIncompleteData". Special Situations: Regarding pregnancy status, the flag variable will be "no" if the respondent answers probably pregnant but responds refused/don't know to whether pregnant. The flag will be "yes" if both are refused/don't know. Regarding gestational age, the variable will be "no" if the respondent can provide due date, date of last menstrual period or weeks pregnant, but "yes" if the respondent provides months pregnant or trimester pregnant.

All women who fall into the Pregnant Eligible and High Tryer and High Non-Tryer groups are asked about their plans to move at the time the T1 or P1 visit is scheduled. If a woman responds that she is moving (before her baby is born or within 2 months if in the High Tryer or High Non-Tryer group) and provides a new address the supervisor will review her case before determining to schedule a T1 or P1 visit (for sub-sampled women) or determine her ineligible.

The algorithm will calculate PPG at the initial Pregnancy Screener based on the respondent'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 has turned 50. Otherwise, if the respondent 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 - 6.30.08



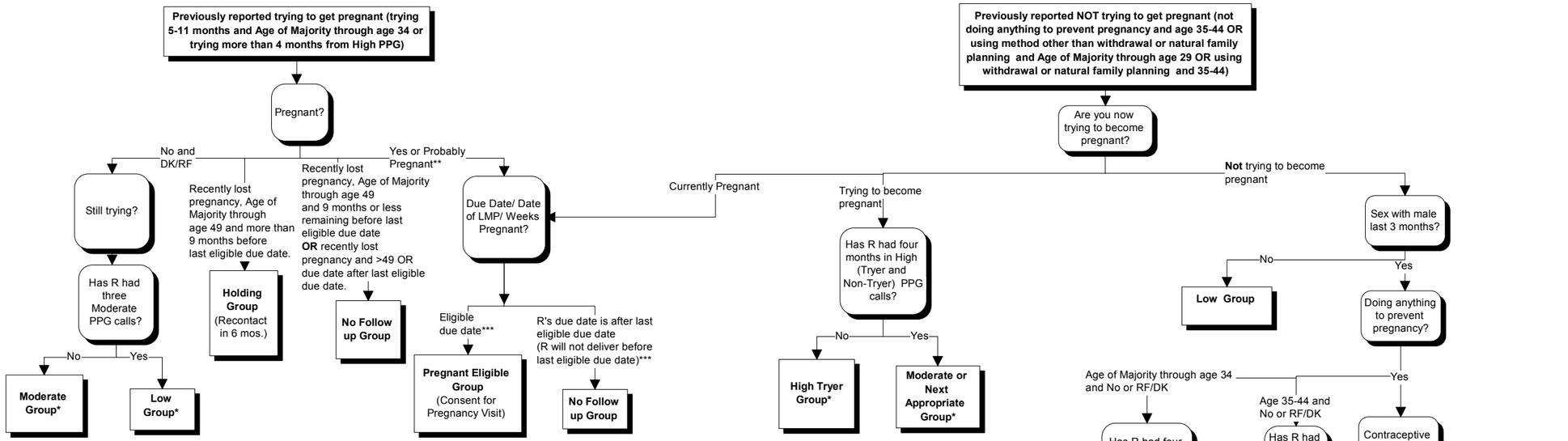
*All women who fall into the Pregnant Eligible Group will be asked about their plans to move at the time the T1 visit is scheduled.
**First and last eligible due dates are based on the dates that screening starts and ends in each segment. The last eligibile due date for all segments in each PSU will be 5 years after the first eligible due date of the segment which was opened last.
***The respondent can spend up to a total of four months in the High Tryer and High Non-Tryer PPGs before being assigned to the Moderate PPG and up to a total of nine months in the Moderate PPG before being assigned to the Low PPG.

The algorithm will determine whether an eligible female is to be sub-sampled for the P1 visit or not. Initially, all participants in the High Non-Tryer and High Tryer Groups will receive the follow up phone calls. When the P1 becomes available, those sub-sampled will receive the preconception consent vist while the rest will only receive the follow up phone calls.

The algorithm will create a flag variable to identify PPG statuses that are created from refused or don't know answers, called "PPGFlagIncompleteData". Special Situations: Regarding pregnancy status, the flag variable will be "no" if the respondent answers probably pregnant but responds refused/don't know to whether pregnant. The flag will be "yes" if both are refused/don't know. Regarding gestational age, the variable will be "no" if the respondent can provide due date, date of last menstrual period or weeks pregnant, but "yes" if the respondent provides months pregnant or trimester pregnant.

The algorithm will calculate PPG based on the respondent'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 reached age 50. For those that would fall into the Moderate, Low or Holding Group, however,if the algorithm calculates the respondent would be 50 at the next scheduled follow up phone call, they will instead be assigned to the No Follow Up group.

Moderate Pregnancy Probability Group Call 6.30.08



*The Moderate Phone Call algorithm requires the incorporation of data on how long the respondent has spent in each PPG. The respondent can spend up to a total of four months in the High Tryer and High Non-Tryer PPGs before being assigned to the Moderate PPG and up to a total of nine months in the Moderate PPG before being assigned to the Low PPG. The respondent can spend up to the entire recruitment period in the Low group, which receives phone calls once every six months. The respondent can also move back up to the Moderate PPG and between the Moderate PPG and Low PPG groups based on the combination of their questionnaire answers and PPG history. The amount of time allowed in the High Tryer and High Non-Tryer PPGs 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. The last eligible due date for all segments in each PSU will be 5 years after the first eligible due date of the segment which was opened last.

The algorithm will create a flag variable to identify PPG statuses that are created from refused or don't know answers, called "PPGFlagIncompleteData". Special Situations: Regarding pregnancy status, the flag variable will be "no" if the respondent answers probably pregnant but responds refused/don't know to whether pregnant. The flag will be "yes" if both are refused/don't know. Regarding gestational age, the variable will be "no" if the respondent can provide due date, date of last menstrual period or weeks pregnant, but "yes" if the respondent provides months pregnant or trimester pregnant.

The algorithm will determine whether or not an eligible female assigned to the High Tryer and High Non-Tryer groups for the first time is to be sub-sampled for the P1 visit. Initially, all participants in the High Non-Tryer and High Tryer Groups will receive only the follow up phone calls. When the P1 becomes available, if sub-sampling is done, those who are sub-sampled will receive the preconception consent and vist while the rest will only receive the follow up phone calls.

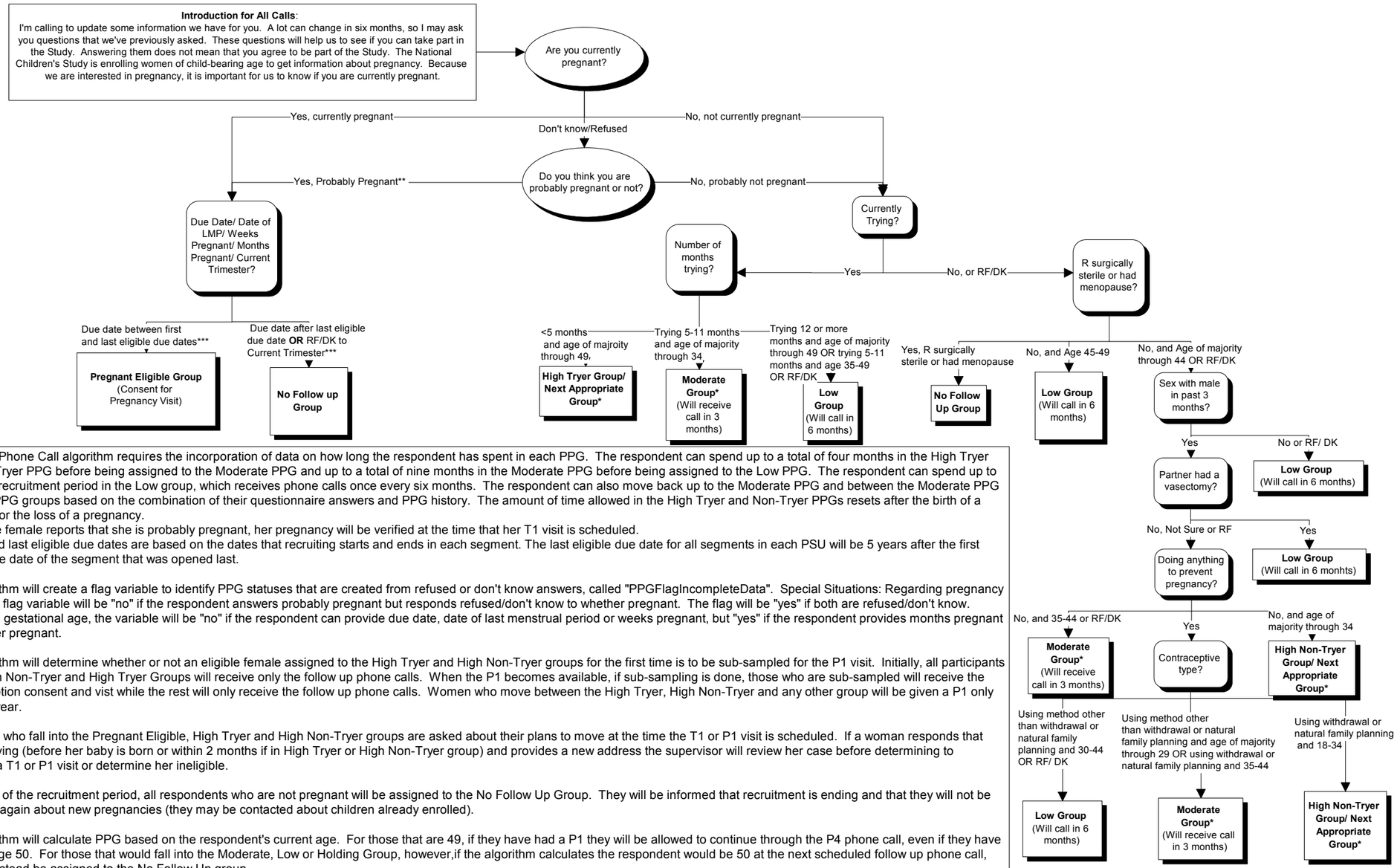
All women who fall into the Pregnant Eligible and HighTryer and High Non-Tryer groups will be asked about their plans to move at the time the T1 or P1 visit is scheduled. If a woman responds that she is moving (before her baby is born or within 2 months if in High Tryer and Non-Tryer groups) and provides 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 Tryer, High Non-Tryer 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 about new pregnancies (they may be contacted about children already enrolled).

The algorithm will calculate PPG based on the respondent'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 reached age 50. For those that would fall into the Moderate, Low or Holding Group, however,if the algorithm calculates the respondent would be 50 at the next scheduled follow up phone call, they will instead be assigned to the No Follow Up group.

Low Call Algorithm 06.30.08



*The Low Phone Call algorithm requires the incorporation of data on how long the respondent has spent in each PPG. The respondent can spend up to a total of four months in the High Tryer and Non-Tryer PPG before being assigned to the Moderate PPG and up to a total of nine months in the Moderate PPG before being assigned to the Low PPG. The respondent can spend up to the entire recruitment period in the Low group, which receives phone calls once every six months. The respondent can also move back up to the Moderate PPG and between the Moderate PPG and Low PPG groups based on the combination of their questionnaire answers and PPG history. The amount of time allowed in the High Tryer and Non-Tryer PPGs 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 recruiting starts and ends in each segment. The last eligible due date for all segments in each PSU will be 5 years after the first eligible due date of the segment that was opened last.

The algorithm will create a flag variable to identify PPG statuses that are created from refused or don't know answers, called "PPGFlagIncompleteData". Special Situations: Regarding pregnancy status, the flag variable will be "no" if the respondent answers probably pregnant but responds refused/don't know to whether pregnant. The flag will be "yes" if both are refused/don't know. Regarding gestational age, the variable will be "no" if the respondent can provide due date, date of last menstrual period or weeks pregnant, but "yes" if the respondent provides months pregnant or trimester pregnant.

The algorithm will determine whether or not an eligible female assigned to the High Tryer and High Non-Tryer groups for the first time is to be sub-sampled for the P1 visit. Initially, all participants in the High Non-Tryer and High Tryer Groups will receive only the follow up phone calls. When the P1 becomes available, if sub-sampling is done, those who are sub-sampled will receive the preconception consent and vist while the rest will only receive the follow up phone calls. Women who move between the High Tryer, High Non-Tryer and any other group will be given a P1 only once per year.

All women who fall into the Pregnant Eligible, High Tryer and High Non-Tryer groups are asked about their plans to move at the time the T1 or P1 visit is scheduled. If a woman responds that she is moving (before her baby is born or within 2 months if in High Tryer or High Non-Tryer 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.

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Appendix C.4

Deleted

Appendix C.5

Outside Groups Consulted

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.

Roster of Members

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Senior Vice President and Medical Director
March of Dimes

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Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health, HHS

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National Institute of Environmental Health Sciences
National Institutes of Health, HHS

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National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention, HHS

Page updated - 05/12/08

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 (HHS) and the U.S. Environmental Protection Agency (EPA). Within HHS, 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 *Eunice Kennedy Shriver* 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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Steering Committee

The Steering Committee provides first level scientific direction to the National Children's Study. It is the arbiter of issues referred to it by the Program Office, the Study Principal Investigators, and the Executive Steering Committee. It is empowered to make protocol modifications that do not change the direction or cost of the Study, subject to confirmation by the Program Office. The Steering Committee may refer management and operational issues to the Executive Steering Committee. The Director of the Program Office serves as the Chair of the Steering Committee.

The Steering Committee is currently comprised of 58 members. Each Study Center (including the Vanguard Centers) has 2 representatives and 1 vote per Center. The Coordinating Center has 3 members, one of whom has a vote. Each of the following members has one vote: 2 members from the Interagency Coordinating Committee, 3 members from the Program Office, and 2 community and participant representatives. There are a total of 32 votes. The Steering Committee structure and decision making process may be revised and restructured when additional Study Centers are awarded and added to the Steering Committee.

The full Steering Committee meets face-to-face at least once a year. Interim meetings by conference call or video conferencing are scheduled as needed. Business of the Steering Committee is considered closed except to the committee members and approved observers.

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Leo Trasande, MD, MPP Department of Community and Preventive Medicine, Mount Sinai School of Medicine

Robin Wilkerson, RN-C, PhD* Department of Women's and Children's Health, University of Mississippi School of Nursing *Rotating Member

Updated May 2008

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

Executive Steering Committee

The Executive Steering Committee is a subset of the full Steering Committee. The Executive Steering Committee carries out the majority of the protocol and operational decision making, referring only those items necessary for full Steering Committee consideration. This committee addresses issues that are budget neutral and topics that do not change the Study's mission.

Voting membership consists of the Principal Investigators from 7 Study Centers; 3 members from the Program Office including the National Children's Study Director, who is the Chair of the Committee; 2 members from the Interagency Coordinating Center; 2 Community/Participant Representatives; and the Principal Investigator for the Coordinating Center. The Co-Principal Investigator for the Coordinating Center will participate on the committee as a non-voting member.

Meetings are held monthly via conference call and face-to-face meetings are scheduled every 2–3 months.

Executive Steering Committee Members

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

Stephen Buka, ScD Department of Community Health, Brown University

Edward B. Clark, MD Department of Pediatrics, University of Utah

Elaine Eaker, ScD
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Barbara Entwisle, PhD Carolina Population Center, University of North Carolina, Chapel Hill

Elaine Faustman, PhD Department of Environmental and Occupational Health Sciences, University of Washington

Alexa Fraser, PhD
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Sarah Knox, PhD National Children's Study Program Office, NICHD, NIH, HHS

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Peter Scheidt, MD, MPH National Children's Study Program Office, NICHD, NIH, HHS

Kenneth Schoendorf, MD, MPH National Center for Health Statistics, CDC, HHS

Stacy Scott In Black Print, Inc.

Updated May 2008

Appendix C.6

Incentive Plan

Incentives by Visit											
	Length of contact in hours	**Types of data collection**									**Planned incentive**[1]
Contact/Type of contact[2,3]		Interview	Physical measures	Biospecimens	Environmental samples	SAQs	Medical Provider Log[5]	Self-collected biospecimens	Self-collected environmental samples	Medical record/Chart abstraction	
Pre-pregnancy											
Pre-conception home visit	3.00	M			H		M	M			$100 monetary incentive
Pre-conception SAQs	1.00					M		M			None
Pre-conception follow-up home visit	1.00		M	M	H		M				$25 non-monetary incentive
Pre-conception--high-- 1st month telephone call	0.25	M					M				None
Pre-conception--high-- 2nd month telephone call	0.25	M					M				None
Pre-conception--high-- 4th month telephone call	0.25	M					M				None
Pre-conception--moderate--3 month phone call	0.25	M									None
Pre-conception--moderate--6 month phone call	0.25	M									None
Pre-conception--moderate--9 month phone call	0.25	M									None
Pre-conception--low--phone call every 6 months	0.25	M									None
Pregnancy											
First trimester home visit--Mother	2.25	M			H		M	M			$100 monetary incentive
First trimester SAQs and biospecimens--Mother	1.00					M		M			None
First trimester follow up home visit--Mother	1.25		M	M	H		M				$25 non-monetary incentive
First trimester home visit--Father	1.25	F		F							$100 monetary incentive
First trimester SAQs--Father	1.00					F					None
First trimester follow-up home visit--Father	1.25		F					F			None
First trimester ultrasound[4] --Mother	1.00		M				M				Ultrasound report and image provided
16-17 weeks telephone call--Mother	0.25	M					M				None
2nd trimester ultrasound--Mother	1.00		M				M				Ultrasound report and image provided
3rd trimester clinic visit--Mother	2.50	M	M	M		M	M				$100 monetary incentive Ultrasound report and image provided
3rd trimester SAQs, environmental samples and biospecimens --Mother	1.00					M		M	H		None
36 weeks telephone call--Mother	0.25	M					M				None

Incentives by Visit

Contact/Type of contact[2,3]	Length of contact in hours	Types of data collection									Planned incentive[1]
		Interview	Physical measures	Biospecimens	Environmental samples	SAQs	Medical Provider Log[5]	Self-collected biospecimens	Self-collected environmental samples	Medical record/Chart abstraction	
Birth											
Delivery hospital visit--Mother/Child	2.00			M, C							For both birth visits combined: $50 monetary inentive--check mailed around 36 week call $25 non-monetary incentive
Pre-discharge hospital visit--Mother/Child	3.00		C	C			C			M,C	
1 month home visit (if birth visit missed)--Mother/Child	3.00		C				C			M,C	Received $50 check mailed around 36 week call $25 non-monetary incentive
1 month home visit (agree to enroll at hospital; enrolled at this visit)--Mother/Child	3.00	M	C		H		C			M,C	$100 monetary incentive $25 non-monetary incentive
Post-natal											
3 month telephone call	0.25	M					C	M			None
6 month home visit--Mother/Child	3.00	M	C		H		C	C,M			$100 $10 non-monetary incentive (baby item)
6 month SAQs and biospecimens--Mother	1.00					M		M			None
6 month follow up home/mail--Mother	1.00				H		C				None
6 month SAQs and biospecimens--Father	1.00					F		F			$25
9 month telephone call--Mother	0.25	M			CC[6]		C				None
9 month by mail--Father	1.00					F					$25 non-monetary incentive mailed with SAQ
12 month home visit--Mother/Child	3.00	M	C	C	H		C	C			$100 monetary incentive $10 non-monetary incentive
12 month SAQs--Mother	1.00					M					None
12 month followup visit--Mother/Child	1.00							C			None
12 month home visit--Father	0.50	F									$100 monetary incentive $10 non-monetary incentive
12 month SAQs--Father	1.00					F					None
18 month telephone call--Mother	0.50	M					C				None
24 month telephone call	0.50	M			CC[6]		C		H		$40 mailed with request for self-collection
30 month telephone call	0.50	M					C				None

KEY: M=Mother F=Father C=Child H=Place of residence CC=Child Care location(s) (Collections in child care centers are done by study staff and do not place burden on the mother, father or child.)

1 The non-monetary incentive value shown on the table reflects a potential value. We anticipate that the PO will determine a value that reflects NCS budget constraints and priorities.

2 Follow-up activity is initiated at in-person visit and requires action after the visit (e.g., return of SAQs and/or environmental samples or biospecimens).

3 See Key for indication of visit participant.

4 First trimester ultrasound is only done by the NCS if the mother does not already have an ultrasound done by her health care provider. If she does, the NCS will request permission to obtain ultrasound report from provider.

5 The Mother completes the medical provider log prior to (high pregnancy probability group only) and throughout her pregnancy; one is completed for the child after birth.

6 Child care centers will be subsampled for visits for data collection.

Appendix C.7

Certificate of Confidentiality

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

06/24/2008

NICHD
Dr. Peter Scheidt
6100 Executive Blvd, Room 5C01
Bethesda, MD 208927510

Dear Dr. Scheidt,

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, 'National Children's Study (NCS)'. Please note that the Certificate expires on 12/01/2016.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, 12/01/2016, you must submit a written request for an extension of the Certificate three months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reasonfor the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the Certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the Certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to:

Steven Hirschfeld, MD PhD
Associate Director for Clinical Research
Eunice Kennedy Shriver National Institute of Child Health and Human Development
31 Center Drive, Room 2A03, MSC 2425
Bethesda, MD 20892-2425
Telephone: (301) 496-0044
Fax: (301) 480-1104

Sincerely,

Steven Hirschfeld, MD PhD

CERTIFICATE OF CONFIDENTIALITY

CC-HD-08-64

issued to

NICHD

conducting research known as

National Children's Study (NCS)

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, Dr. Scheidt to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Scheidt is primarily responsible for the conduct of this research, which is supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development..

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1 are enrolled in, employed by, or associated with the NICHD and their contractors or cooperating agencies and

2 have in the course of their employment or association access to information that would identify individuals who are the subjects of the research pertaining to the project known as, National Children's Study (NCS)

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

The National Children’s Study is a longitudinal cohort study designed to examine the effects of environmental influences on child health and development. Environment is broadly defined to include biological, physical, chemical, and social/cultural influences on children’s health and development. The study is based on a nationally-representative sample of 100,000 children. Priority outcomes include obesity, diabetes, and physical development; injuries; asthma; pregnancy-related outcomes; child development and mental health.

A Certificate of Confidentiality is needed because sensitive information will be collected during the course of the study. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

All subjects will be assigned a code number and identifying information and records will be kept in locked files at the Institution.

This research will begin on 10/01/2008 and is expected to end on 12/01/2016.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

'Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.'

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject’s legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

CERTIFICATE OF CONFIDENTIALITY
CC-HD-08-64
issued to
NICHD
conducting research known as
National Children's Study (NCS)

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on 12/01/2016. The protection afforded by this Confidentiality Certificate is permanent with respect to subjects who participate in the research during the time the Certificate is in effect.

Date: 06/24/2008

_____

Steven Hirschfeld, M.D., Ph.D.
Associate Director for Clinical Research
Eunice Kennedy Shriver National Institute
of Child Health and Human Development

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. 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 (estimated births) 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 (estimated births). 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. This contact will be used to update the status of enrolled women's likelihood of pregnancy and thus her schedule for follow-up visits. 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 again at least once during the enrollment period. (Although this is the current plan, alternatives involving more frequent contact are currently under consideration.)

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 late 2008, data collection in the first wave of additional PSUs is planned to begin in early 2010 with the release of the second and third waves to follow later.

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.

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 (or chunks), 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 eligible women are targeted for enrollment: women who are in their first trimester of pregnancy and women between the age of majority and 49 years of age who are at some probability of becoming pregnant during the 4-year enrollment period. After the 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 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. (See Appendix A.1.1.b questions PS038 to PS041t). 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" (See Appendix A.2.1.h) 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.

QUESTIONNAIRE ADDRESSING: EVALUATION OF COMMUNITY ENGAGEMENT ACTIVITIES

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

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.

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.

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

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.

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

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.

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.

Sources:

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OMB #: 0925-xxxx
Expiration Date: xx/xxxx

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.

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

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 C: REPORT OF FINDINGS AND REFERRALS

1. Overview

Participants in the National Children's Study (NCS) will be informed through the consenting process that only those results obtained during a given visit will be provided to the respondent. The Visit Information Sheets will specify exactly which tests results respondents will receive during a given study visit. For the first stage of the study (i.e., pre-pregnancy through child age 3), these test results will be limited to height/length, weight, body mass index, and blood pressure, depending upon the age of the participant as described below. Field researchers will provide results to respondents through the hard copy document, *Report of Findings*, as well as referral information at the time of the visit.

This strategy of revealing findings to study participants reduces misunderstandings of study practices as replacing regular medical care. However, there may be occasions where other test results completed after the visit indicate risk to respondents or communities. In these scenarios, the NCS director will be advised by the Data Safety and Monitoring Board (DSMB) and relevant IRBs through established information flow. Procedural details for such occasions are described below.

2. Report of Findings

Participants will receive a written *Report of Findings* after completing a physical exam, either at home or at a clinic. This report will include height/recumbent length, weight, body mass index, and blood pressure, depending upon the age of the participant. See Table 1. For persons 6 and older, it will also include a brief interpretation of the visit results based on predetermined criteria as cited in the *Report*. These criteria will take into account the age and sex of the participant. The *Report* also lists a toll-free referral number for participants to use for follow-up questions about results. The Visit Coordinator will review the results verbally with the participant.

Table 1. Age Categories by Physical Measurement Reported

Measure	Age
Length	Birth through age 3
Height	3 and older
Weight	Birth and older
Body Mass Index	20 and older
Blood pressure	12 months and older

Ultrasound images will also be provided to the mother for each study-scheduled visit (i.e., trimester 1, if not already scheduled; trimester 2 and trimester 3).

Recumbent length/height and weight: Participants will receive recumbent length of children up to and including 3 years of age, and height for persons age 3 and older (both forms of measurement are taken at age 3). All participants will be given their weight. Although measurements are recorded in metric units for data collection purposes, the results for the *Report of Findings* will be converted to English units. These measurements will be printed on the hard copy report along with a brief interpretation of the results.

Body Mass Index (BMI): BMI, adjusted for sex, will be calculated for persons ages 20 years and older. The technician will check the appropriate statement based on the body mass index percentile. Table 2 shows the statements for this age group associated with each body mass index category.

Table 2. Statements by BMI categories for report of findings (20 years and older)

Body Mass Index	Report of Findings Statement for weight status based on 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:"
Below 18.5	Underweight
18.5–24.9	Normal
25.0–29.9	Overweight
30 and above	Obese

Blood pressure: Blood pressure will be given to participants ages 6 and older. Relevant standards vary by age, as described below.

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.[1] The tables display systolic and diastolic blood pressure results by percentile of height for males and females ages 6 through 17 years. Systolic and diastolic blood pressure are then categorized by range and assigned an interpretation based on clinical standards, as cited in Table 3. If the results are above the normal range (categories 3—4), referral procedures will be followed as described in section 3.

Table 3. Statements by result category for blood pressure report of findings (ages 6-17)[2]

Category	**Report of Findings Statement** *"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.*

For persons 18 and older, systolic and diastolic blood pressure are categorized by range and assigned an interpretation based on clinical standards for this age group, as cited. For example, Table 4 shows the blood pressure category (1–5) for the systolic and diastolic blood pressure combination. The category number indicates the statement to be used for the report of findings. If the results are above the normal range (categories 3—5), referral procedures will be followed as described in section 3.

[1] 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 4. 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. [21]
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.

Ultrasound image: Participating women will be given an image from each of the ultrasounds performed as part of the study. Ultrasounds are planned for each trimester of the participant's pregnancy. However, a first trimester ultrasound will not be scheduled on behalf of the study if the participant has a first trimester ultrasound already planned as part of her prenatal care and agrees to share those ultrasound results with the study. In that case, the study would not provide an image of that first trimester ultrasound to the participant. Referral numbers will be available from the field technician for participants to use for follow-up questions, but the participant is informed through the consenting process that ultrasound image interpretation will not be provided and that ultrasounds scheduled for study purposed do not replace medical care.

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

Exhibit 1. Sample Report of Findings (Birth through 2 years)

Participant name:

Date of visit: ☐☐/☐☐/ 20☐☐

Body Measurements

Recumbent length: ☐☐☐.☐ cm.

☐ Could not obtain

Weight: ☐☐☐ pounds ☐☐ ounces

☐ Could not obtain

Blood Pressure and Heart Rate

Blood pressure: ☐☐☐ / ☐☐☐ mmHg

☐ Could not obtain
☐ Not measured at this visit (less than 1 yr of age)

Heart rate: ☐☐☐ beats per minute

☐ Could not obtain
☐ Not measured at this visit (less than 1 yr of age)

Your child's blood pressure today is:* ☐ N/A

☐ Within the normal range
☐ Above the normal, in the pre-hypertensive range
☐ High
☐ Very high
☐ Severely high

We recommend that: ☐ N/A

☐ No action is needed.
☐ You discuss these findings with a healthcare provider at your child's next visit.
☐ Your child sees a healthcare provider within 2 weeks.
☐ Your child sees a healthcare provider immediately.

Name of data collector:

Staff ID: ☐☐☐☐☐☐☐

* Categories are based on the National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents, The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents. Pediatrics 2004 114: 555-576.

The purpose of the study examination 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.

If you have any questions about the information on this form, please see the **Local Contact Sheet.**

Exhibit 2. Sample Report of Findings (3 years through 19 years)

Participant name:

Date of visit: ☐☐/☐☐/ 20 ☐☐

Body Measurements

Weight: ☐☐☐ pounds
☐ Not measured at this visit
☐ Could not obtain at this visit

Recumbent length*: ☐☐☐.☐ cm.
**age 3 only* ☐ Could not obtain

Height: ☐ feet ☐☐ inches
☐ Not measured at this visit
☐ Could not obtain at this visit

Blood Pressure and Heart Rate

Blood pressure: ☐☐☐ / ☐☐☐ mmHg
☐ Could not obtain at this visit

Heart rate: ☐☐☐ beats per minute
☐ Could not obtain at this visit

You / your child's blood pressure today is:**

☐ Within the normal range
☐ Above the normal, in the pre-hypertensive range
☐ High
☐ Very high
☐ Severely high

We recommend that:
☐ No action is needed.
☐ You discuss these findings with a healthcare provider at you/your child's next visit.
☐ You/your child see a healthcare provider within 2 weeks.
☐ You/your child see a healthcare provider immediately.

Name of data collector:

Staff ID: ☐☐☐☐☐☐☐

** (3 through 17 years) Categories are based on the National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents, The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents. Pediatrics 2004 114: 555-576.

** (18 years and above) 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 examination 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.

If you have any questions about the information on this form, please see the **Local Contact Sheet.**

Exhibit 3. Sample Report of Findings (20 years and above)

Participant name:

Date of visit: ☐☐/☐☐/ 20 ☐☐

Body Measurements

Weight: ☐☐☐ pounds
☐ Not measured at this visit
☐ Could not obtain at this visit

Height: ☐ feet ☐☐ inches
☐ Not measured at this visit
☐ Could not obtain at this visit

Body Mass Index: ☐☐.☐
☐ Not measured at this visit
☐ Could not obtain at this visit

Body Mass Index (BMI) is a number calculated from a person's weight and height. It 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 BMI 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

Name of data collector:

Blood Pressure and Heart Rate

Blood pressure: ☐☐☐ / ☐☐☐ mmHg
☐ Could not obtain at this visit

Heart rate: ☐☐☐ beats per minute
☐ Could not obtain at this visit

Your blood pressure today is:*

☐ Within the normal range
☐ Above the normal, in the pre-hypertensive range
☐ High
☐ Very high
☐ Severely high

We recommend that:
☐ No action is needed.
☐ You discuss these findings with a healthcare provider at your next visit.
☐ You see a healthcare provider within 2 weeks.
☐ You see a healthcare provider immediately.

Staff ID: ☐☐☐☐☐☐☐

* 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 examination 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.

If you have any questions about the information on this form, please see the **Local Contact Sheet.**

3. Referrals

Although the purpose of the NCS examinations is data collection, not diagnosis or treatment, physical exams may yield clinically significant findings available at the time of visit that warrant further medical attention. Below we describe procedures in these scenarios.

The only exam result available at the end of the exam to establish the need for a referral is blood pressure. Exam results are classified into three referral levels. Referral letters and forms will be given for results that fall in Level 1 and 2 categories.

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

Level 2: Major medical findings require attention by a health care provider within the next two weeks. The examinee may experience adverse health 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.

Level 1 findings: 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). The Visit Coordinator verbally will instruct the participant to see his/her health care provider immediately. 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. If the examiner believes the participant is in imminent danger, he or she will also call 911 for medical assistance.

Level 2 findings: In the case of Level 2 findings, the Visit Coordinator will be responsible for providing the respondent with a standard referral letter (Exhibit 3), a referral form with specific information regarding the results (Exhibit 4), and instructions to see his/her 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, 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.

Exhibit 4. Sample Standard Referral Letter for Physical Measure Results at Levels 1 or 2

Date of visit: ☐☐/☐

☐/ 20 ☐☐

Dear Healthcare Provider:

_____is participating in the National Children's Study
{Name of participant}

which is led by the U.S. Department of Health and Human Services—through the National Institutes of Health and the Centers for Disease Control and Prevention—and the U.S. Environmental Protection Agency. One of the objectives of the National Children's Study is to obtain information on the health and development of U.S. children. **This examination is intended to collect health measures for research and is not a complete physical exam. No attempt has been made to diagnose or treat medical conditions of the participant.** As a result of the testing that was done, a finding was revealed that was outside of the study's medically acceptable range. The finding disclosed to you is done so with the participant's permission.

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 pressures were calculated from the remaining readings. The results are recorded below. Referral categories are based on:

- Ages 6–17 yrs: National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents, The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents published in 2004.
- Ages 18 and above: Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure published by the National Institute of Health in 2003.

  Systolic blood pressure: ☐☐☐ mmHg

  Diastolic blood pressure: ☐☐☐ mmHg

  Heart rate: ☐☐☐ beats per minutes

Comments:

_____

_____

_____

_____
Signature of data collector

If you have any questions about the information on this form, please see the **Local Contact Sheet.**

_____
Print name of data collector Staff ID: ☐☐☐☐☐☐☐

4. DSMB-Directed Report of Findings

There may be circumstances where test results indicate risk to respondents or communities. In these cases, the NCS Data Safety and Monitoring Board (DSMB) would be consulted. The DSMB makes recommendations to the NICHD Director, the NCS Director, and the Ethics Advisory Committee; Subcommittee of Federal Advisory Committee concerning protocol and operational issues to ensure the safety of participants and the validity and integrity of the data. It is particularly involved in emerging results that should be communicated to the study participants and/or community.

The DSMB will define criteria to be used to reveal findings to affected persons. These criteria will reflect, among other factors, the time tag between collection of data and analysis, and clinical relevance of the findings, such as medical recourse to address the expected probability of harm. These recommendations are reported to the NICHD, any additional study sponsors, the clinical investigators, any data coordinating centers and the IRBs of participating institutions through an established information flow.

Five to ten persons independent of the NCS study are appointed by the NICHD director to serve on this Board. Normally, members are not employees of the NIH or from the same institution as the Principal Investigator(s).These persons are expected to have experience in longitudinal epidemiologic studies, ethics, biostatistics, pediatrics, environmental toxicology, data disclosure and genetics. Staffing for this Board is expected to be complete well in advance of field operations. The charge, operating procedures, and responsibilities of the NCS DSMB will be the first task before the Board, and are expected to align closely with those described in the draft guidance found at http://www.fda.gov/cber/gdlns/clindatmon.pdf.

Should the DSMB determine that test results that otherwise would not have been shared should be revealed to participants, we would recommend the following implementation approach 1) a letter indicating that the NCS has some test results that we would like to share with the respondent would be sent by return receipt to the respondent; 2) a phone call would be placed to the respondent 2-3 days after shipment to ask if the respondent received the letter, if s/he had any questions about the contents of the letter, and if s/he would like the test results to be mailed; 3) if the respondent would like test results sent, a letter requiring signature upon delivery would be sent by FedEx or similar to the respondent; 4) a follow up call would be placed 2-3 days after expected delivery to discuss the contents of the letter with the respondent and provide referral

information as appropriate. Telephone contactors would be specially selected and trained for this task, including bilingual contactors as needed.

We allow that in some cases, some tracing activity would need to be performed to locate a respondent, especially in cases of prior study non-response, and in some of these cases, follow up will not be successful. We will make efforts, however, to minimize this.

Appendix C.12

IRB Certifications

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Office of the Clinical Director
National Institute of Child Health
and Human Development
CRC; Room 5-2571
10 Center Drive MSC 1832
Bethesda, Maryland 20892-1832
FAX: 301 402-1073

MEMORANDUM

DATE: June 26, 2008

TO: **Peter Scheidt, M.D., MPH**

FROM: Gilman Grave, MD

Through: Stephen G. Kaler, MD MPH
Clinical Director, NICHD

SUBJECT: Disposition from 06/25/08 NICHD Institutional Review Board Meeting

Below please find the disposition concerning the review of your protocol considered this week by the IRB. Thank you very much for submitting this interesting study.

NEW PROTOCOL

National Children's Study (The findings of the National Academy of Science Review, and the response to those findings.)
Principal Investigator: Peter Scheidt
Protocol Title: The National Children's Study – Pilot protocol.
Protocol number: New Application

Discussion and Disposition: The Board was favorably inclined in its consideration of the National Children's Study. However, it was understood that the final protocol and consent procedures were not yet finalized. Therefore, the Board agreed to table consideration of the protocol pending receipt of the updated protocol, consent form and the script for the consent video. The vote was 6 in favor, 1 opposed (the member preferred to defer consideration of the protocol without a formal vote).

Recommendations:

1. Provide updated protocol, consent form and script of consent video. Highlight changes
2. Provide list of DSMB members (including affiliations) for IRB review and

approval.

3. Provide a list of ongoing study working group members and affiliations
4. Provide an update to the IRB on at least a biannual basis.
5. Provide a plan for addressing health disparities noted in the IOM Report.
6. Provide a summary of the public comments received on the protocol.

THIS PROTOCOL EXPIRES JUNE 24, 2009

WESTAT
AN EMPLOYEE-OWNED
RESEARCH CORPORATION

MEMORANDUM

TO: Elaine Eaker and Paul Hurwitz January 29, 2008

FROM: Kerry Levin
Acting Chair, Institutional Review Board

SUBJECT: IRB Review and Approval
National Children Study
Contract No. HHSN275200503395C
Project 8208
FWA5551

On January 8, 2008, the Westat Institutional Review Board (IRB) conducted its review of the following: **National Children's Study (NCS)**, Contract No. HHSN275200503395C, Project 8208. This review covers all procedures before and during the mother's pregnancy through the birth visit and the one month visit. Data collection activities with the mother, father and child after the one month visit will be presented and addressed at a subsequent IRB meeting. Westat's IRB reviews all studies involving human research before activities may begin under 45 CFR pt 46.

Due to the complexity of the study, project staff organized several informational steps to help familiarize the Board with the goals and objectives of the study prior to a voting decision. First, an informational session during the December 11th IRB meeting was held. During this meeting, project staff provided the Board with an overview of the project and presented a sample of the video consent process. Following this session, the IRB Board Chair circulated a series of questions from Board members to project staff. The final review of study materials and procedures took place during the January Board meeting which was also included a discussion of the answers provided to all of the questions and requests for further clarification regarding answers to some questions.

Following the January Board meeting, additional information was submitted by the NCS project staff to supplement answers to questions which had been submitted previously. These answers now appear in the final record and are included as an attachment to the study protocol. Some of the answers will require modification to the study protocol at a future time. It is anticipated that a copy of the revised protocol reflecting the answers to questions will be sent to this IRB for the record.

Lastly, even if the protocol does not change, if Westat's role with regard to data collection should change, those aspects of the study must be reviewed by the Westat IRB.

The Board determined that NCS presents no greater than minimal risk to the pregnant woman and their unborn children. It was also determined that the number of ultrasounds being conducted does not place the women or child at increased risk, based on documentation provided to the Board.

Because this study presents no greater than minimal risk, the Board waives the requirement for the father's consent for the child or unborn fetus [45 CFR 46.116 of Subpart A and 46.408 (b)]. The father however, will be required to provide written consent for his own participation in the study. In addition, a waiver for permission from both parents has been granted for emancipated pregnant minors as long as it does not conflict with local jurisdiction requirements. Each Study Center will be responsible for adherence to their local jurisdictional requirements regarding the consent and enrollment of pregnant minors. The Coordinating Center will prepare procedures to be used when the pregnant minor is legally allowed to provide consent, and when she is not, and the Study Centers will be required to adhere to their local laws.

Based upon this approval, the project must submit a Certificate of Confidentiality to the IRB as soon as it is received; no reference to the Certificate may be made to the women whose consent for enrollment is sought until the Certificate is obtained.

It is understood that no data collection will begin until approval of the study by the NICHD IRB. In addition, no data collection will begin at any study center site until the approval of the study, including all activities of the study center and their subcontractor or organizations, by that Center's IRB. It is anticipated that the NICHD agency IRB will serve as the central NCS IRB to review any protocol changes from the package approved here by the Westat IRB. Any such approvals of changes made by the NICHD IRB will be transmitted to the Westat IRB for our records and use in oversight of Westat's Coordinating Center activities.

In accordance with 45 CFR 46, the Board unanimously approved this study for the phases submitted, which includes procedures before and during the pregnancy of the mother, up to the birth of the child.

You are obligated to submit the study for an annual review on or before January 29, 2009. In the interim, you are responsible for notifying the Office of Research Administration as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board

WESTAT
AN EMPLOYEE-OWNED
RESEARCH CORPORATION

MEMORANDUM

TO: Elaine Eaker and Paul Hurwitz February 11, 2008

FROM: Kerry Levin
Kerry Levin
Acting Chair, Institutional Review Board

SUBJECT: ADDENDUM to approval letter dated 01-29-08 (CORRECTED)
National Children Study
Contract No. HHSN275200503395C
Project 8208
FWA5551

On January 29, 2008, the Westat Institutional Review Board (IRB) assigned full approval of the following: **National Children's Study (NCS)**, Contract No. HHSN275200503395C, Project 8208. The approval covered all procedures before and during the mother's pregnancy through the birth visit and the one month visit. Data collection activities with the mother, father and child after the one month visit will be presented and addressed at a subsequent IRB meeting. Westat's IRB reviews all studies involving human research before activities may begin under 45 CFR pt 46.

Because this study presents no greater than minimal risk, requests for five waivers of informed consent were granted by the board. The first three requests described below are waivers for *documentation* of informed consent. The remaining two requests are waivers to allow signed informed consent from only one parent or guardian since the IRB determined that permission of one parent was sufficient. However, while discussed at the board meeting, explicit descriptions of each waiver were inadvertently omitted from the approval letter. Therefore, each waiver is listed below:

1. A waiver of the requirement for documentation of informed consent (obtaining a signed consent form) for the enumeration stage. This step is designed to locate households containing potentially eligible women for the Study. IRB regulations permit waiver of documentation of informed consent when the research presents no more than minimal risk [45 CFR pt. 46.116 (d) 46.117 (c) (2)].

2. A waiver of the requirement for documentation of informed consent (obtaining a signed consent form) for the screening stage. This step is only designed to determine the eligibility of women for the study. The vast majority of women will not be eligible for the study. IRB regulations permit waiver of documentation of informed consent when the research presents no more than minimal risk [45 CFR pt. 46. 116 (d) 46.117 (c) (2)].

3. A waiver of the requirement to obtain a signed consent form for each specific study visit after enrollment. The project will obtain signed informed consent at enrollment, using

either the video or the paper form, for eligible participants who choose to join the study. IRB regulations permit waiver of documentation of informed consent when the research presents no more than minimal risk and participants are provided with written information regarding the research[45 CFR pt. 46. 116 (d) 46.117 (c)(2)].

4. A waiver for both parents of the unborn child to sign the consent form for enrollment of pregnant women and their unborn children into the study. The Board waives the requirement for the father's consent for the child or unborn fetus [45 CFR 46.116 of Subpart A and 46.408 (b)]. The father however, will be required to provide written consent for his own participation in the study.

5. A waiver for both parents of pregnant minors to sign the consent form for enrollment of pregnant minors into the study as long as it does not conflict with local jurisdiction requirements. *45 CFR Part 46, Subpart D provides for "Additional Protections for Children Involved as Subjects of Research." The requirement for parental permission may be inappropriate in some cases. Examples include research involving older adolescents who, under applicable law, may consent on their own behalf*. The Coordinating Center will prepare procedures to be used when the pregnant minor is legally allowed to provide consent, and when she is not. Each Study Center will be responsible for adherence to their local jurisdictional requirements regarding the consent and enrollment of the pregnant minor.

Note: All information included in the approval letter date January 29th, 2008 remains unchanged.

cc: Institutional Review Board