Date: _____
Principal Investigator: _____
Application Number: _____

Johns Hopkins Medicine - eForm A

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1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

The National Children's Study (NCS) is a multi-year research study that will examine the effects of environmental influences on the health and development of more than 100,000 children across the United States, following them from before birth until age 21. With dramatic demographic changes in the population of children and families in the U.S., it is incumbent on the National Children's Study to accurately measure disparities in regard to race, ethnicity, discrimination, health literacy, and access, utilization, and quality of health services. It is also critical to have valid measures that are appropriate for families who may not speak English, have low health literacy and are from diverse backgrounds. The NCS has initiated several formative research projects which are short term and will provide data to address specific technical questions and research questions for the Main Study. Our local National Children's Study Center is conducting one such formative research project with pregnant and parenting mothers. The purpose of this formative study is to assess the validity and stability of measures of health literacy, discrimination, parenting self-efficacy, and health care access, utilization, and quality among diverse populations in the United States for potential inclusion in the NCS. In addition, the study will assess the acceptability and feasibility of saliva collection from mothers and children in diverse populations and will explore biobehavioral responses that place children at increased risk for poor health outcomes.

In this formative study we will recruit pregnant and parenting women to complete interviews in 2 phases (cognitive interviews and primary data collection) designed to inform measure development and validity and stability of the measures in a large, diverse sample of women as one of five participating NCS sites in the United States. The collaborating NCS sites in California, Florida, Hawaii, and Maryland provide diverse populations for achieving the study aims. Demographically these study sites have high concentrations of African American (AA) Black, Latino/Hispanic, Asian and Pacific-Islander (AAPI) families. We propose to engage these communities to assess content, criterion and construct validity of measures and adapt measures as necessary. Once developed, these can be combined with prospective measures in the main NCS of mental health, physical health, and allostatic load to accurately examine health disparities with health literacy as potential mediator of poor health outcomes.

2. Objectives

1. To assess content validity, translate and test measures of health literacy, discrimination, parenting self efficacy and access, utilization, and quality of health services in diverse populations using cognitive interviewing and a process of adaptation, translation and back translation and testing.

2. To assess criterion validity of the Newest Vital Sign (NVS) health literacy instrument by measuring agreement with Test of Functional Health Literacy in Adults (S-TOFHLA) scores in diverse populations including African American, Spanish-speaking Latino, and English-speaking Asian and Pacific Islanders.

3. To assess construct validity of health literacy measures in influencing parenting and access, utilization, and quality of health services in diverse populations.

4. To assess stability in health literacy, discrimination and parenting self efficacy among first time parents from pregnancy to postnatal periods to inform the timing of construct measurement for NCS.

5. To assess the validity of the Experiences of Discrimination (EOD) measure in diverse populations with consideration of a) simplifying the questions further, b) deciding on the optimal reference timeframe, i.e., the current instrument asks the timeframe of "ever" experiencing discrimination, and c) deciding on optimal mode of delivery.

6. To assess the biologic and behavioral responses that place individual children at increased risk for both short-term and long-term poor health outcomes and disease utilizing saliva measurement of stress and inflammatory/immune markers and cotinine in mothers prior to and after delivery and in their children.

7. To assess the acceptability and feasibility of saliva collection from mothers and young children in a diverse population.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

The goal of the National Children's Study is to understand the impact of environmental influences on the health outcomes and development of children and also to identify factors that contribute to disparities in health outcomes of children. There is early evidence that health literacy, discrimination, parenting self-efficacy, health care access, utilization, and quality are key components that influence health and developmental outcomes in children.

Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (US HHS). Limited health literacy affects people of all ages, races, incomes, and education levels, but the impact of limited health literacy disproportionately affects lower socioeconomic and minority groups. It affects people's ability to search for and use health information, adopt healthy behaviors, and act on important public health alerts.

Limited health literacy is also associated with worse health outcomes and high costs (Berkman). According to the American Medical Association, poor health literacy is a stronger predictor of a person's health than age, income, employment status, education level, and race (AMA).

It is estimated that over 90 million adults have a limited understanding of basic health information and services and a half of parents have difficulty reading and understand patient education materials and many have difficult comprehending a medical advice. Health literacy is a greater problem for minority and immigrant parents which are a growing proportion of the population. Systematic reviews have found that children whose parents had low literacy often had worse health outcomes and is thought to be a major mediator of health disparities through parenting self efficacy or behavior or utilization of health services.

Research has demonstrated the ongoing contribution of race and racial discrimination to health disparities in the United States. However, the longitudinal impacts of racial discrimination on observed child health disparities have received little study except in demonstrations of added risk for lower birth weight infants among minority women who perceived racism (Mustillo, Collins). A recent systematic review of literature by Patcher and Coll designed to identify empirical studies that evaluate racial discrimination as a predictor of child health outcomes confirmed that 1) there are a limited number of studies evaluating the relationship between racial discrimination and child health generally, 2) most work examined behavioral and mental health outcomes rather than the biophysical effects, 3) most of the work has been limited to African American populations, and 4) this limited research has focused on the experiences of youth experiencing personally-mediated racism with little research on the impact on younger children (Pachter).

It is postulated that health literacy may influence outcomes through parenting self efficacy or behavior. One domain in which self agency may play a significant role is parenting. Parenting self agency refers to parents overall confidence in their ability to act successfully in the parental role. This include parents perceptions of their ability to manage their child's behavior and to resolve problems with their child. We propose to measure Parenting Self Agency (Dumka), Maternal Self-Efficacy (Teti) and parenting behaviors expected and not expected to be associated with health literacy to assess subtypes of construct validity; convergent and discriminant validity. It is postulated that health literacy influences health outcomes through utilization of health services. We intend to review and select measures on access to and utilization of primary care, specialty, emergency hospital, after hours and ancillary services, access to a medical home, and unmet needs.

In the past two decades, a major focus in developmental science has been to advance our understanding of why when exposed to adverse experiences or circumstances some mothers and children are placed at risk but others are resilient (Cicchetti). The contemporary conceptual models constructed to explain this general phenomenon involve the notion that individual differences in biological sensitivity to context play a central role (Boyce; Belsky). A key assumption is that reactivity and regulation of the psychobiology of the stress response moderate the link between early adversity (e.g., distress, novelty, uncertainty, threat, neglect-abuse) and psychosocial adjustment and health (Gunnar). The majority of research has focused on the psychobiology of the stress response (Chrousos).

With known racial/ethnic disparities in health outcomes there has been increased focus on the mechanisms creating these disparities. There is growing evidence that racial discrimination (both individual and institutional) as a social stress on groups of children and families can influence psychology and physiology in addition to health behaviors, such as eating habits, activity levels, and substance use and abuse. Discrimination may affect the child directly or affect their parents, which in turn influences child health. Research has demonstrated the biological impact of social processes such as discrimination with the finding of increased stress hormones among those who have experienced discrimination (Sanders Phillips).

Biological and behavioral responses place individual children at increased risk for both short-term and long-term poor health outcomes and disease.

The widespread integration of stress measurements into developmental science is due, at least in part, to the fact that the activity of these stress-responsive systems, and systems they influence, can be assessed non-invasively using saliva as a biospecimen (Granger). The non-invasive nature of saliva collection enables samples to be collected without introducing procedure-related stress into the measurement process. Correspondingly, multiple samplings can be accomplished over time and in special populations, and circumstances. This study will incorporate salivary analytes to increase our understanding of biobehavioral responses to stress that may influence maternal and child health outcomes. This provides a unique opportunity to advance our understanding in several important ways. The advances are oriented around that project's focus on racial/ethnic and socioeconomic differences in features of the experience of pregnancy, maternal behavior and parenting stress, developmental milestones in early child development, and health disparities. Proximal and distal features of the social environment are thought to interact with intrinsic individual differences to influence biological sensitivity to context. Many of these social forces are similar to those linked to racial/ethnic and socioeconomic health disparities. They include social isolation, lack of control and contingency and social support, violence, discrimination, challenging and changing social relationships, and restricted access to health care. Variation in these processes has been associated with negative emotional states, cognitive deficits, problem behavior, and a variety of metabolic and immune-related processes. Alone, or particularly in combination with other commonly collected measures of social forces and family relationships, salivary analytes have the potential to advance our understanding about maternal and child health and development. This study will also test the acceptability and feasibility of saliva collection from mothers and young children in a diverse population.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

Phase I: Cognitive Interviewing

Fifty women with children 0-5 years will be recruited to complete cognitive interviews at our Baltimore site with a total of 100 participants across other NCS sites. The interviews will be conducted with mothers from each of the following racial/ethnic groups: African American, Central American Latino, Mexican American Latino, Caribbean Latino and AAPI. The Baltimore site will focus on data collection among African American women given the demographics of the city. Participants will be recruited from Johns Hopkins through flyers and listserve announcements to faculty and staff and patients of Harriet Lane Clinic.

A structured interview guide will include questions about general concepts of the measures as well as specific questions from established measures on health literacy, discrimination, acculturation, education, and stress. Cognitive interviewing explicitly focuses on the cognitive processes that respondents use to answer questions. Verbal probing will be utilized to delve into the associated cognitive and socio-cultural processes. In addition, participants will provide input about the appropriate approach to community members in the field, issues that may be missed by the measures, and format of delivery (in-person interview, CAPI, ACASI). The interview is attached and will be no longer than 1.5 hours in length.

Phase II: Primary Data Collection:
In order to field test measures, two groups of women will be recruited from obstetric and pediatric primary care sites:

1. First time prospective mothers greater than 20 weeks gestation and
2. Mothers/guardians with children age 0-5 years

The Johns Hopkins Ob Gyn clinics, Harriet Lane Clinic and Lancaster Pediatrics have agreed to be recruitment sites (see letters of participation). Clinic staff will not consent or interview participants. The interview will be conducted at Johns Hopkins, the clinical site, or at a home or community site.

After obtaining informed consent, first time prospective mothers will be interviewed during pregnancy at Time 1 (T1) and 6 months later at Time 2 (T2). Mothers/guardians with children 0-5 years of age will be asked to complete a single interview. The interview mode will primarily be a web-based computer assisted personal interviewing (CAPI) with the interviewer asking questions and entering answers into the computer, with some components utilizing computer assisted self interviewing (CASI with participant reading questions on the computer and answering directly on the computer) and audio assisted self interviewing (audio-CASI with participant hearing questions on headphones and answering directly on the computer). The interview will be up to 1.5 hours in length.

Participants will be asked to provide demographic data such as race/ethnicity, language use, socioeconomic status (SES), and education level. Participants will receive a battery of measures outlined in the attached measures table. These include measures of health literacy, discrimination, acculturation, parenting, health and health behavior, social support, neighborhood characteristics, stress and health access, utilization and quality of health services. The T1 measures are included but are not all perfectly formatted as this is being done for laptop CAPI, CASI and ACASI administration.

As a full service professional data collection organization, Battelle has been subcontracted for the data collection for this portion of the formative research project including recruiting and all interviewing at Hopkins and non-Hopkins sites. Battelle is one of the world's oldest and largest independent contract research organizations and has been in existence since 1929. One specialized Battelle group is the Centers for Public Health Research and Evaluation (CPHRE). CPHRE has proven its capabilities of providing quality resources to our clients directly or by supporting more than 250 health-related projects annually for the Public Health Service, industry, and academia. Over 80 percent of this work involved investigations of women, children, or other minority populations. CPHRE has annual, world-wide business revenue totaling almost $16 million and a staff of more than 200 technical, management, and support professionals providing leading-edge technology to meet the needs of our clients. Some illustrative work is presented below:

For “Adolescent Development in High Risk Neighborhoods”, Battelle staff collected baseline data from a sample of 6^{th}–9^{th} grade students who attended a junior high school in Baltimore City. Interviews were conducted on laptop computers using ACASI (audio computer-assisted self interviewing). There was a three year follow-up period where contact was maintained with the sample through regular mailings and phone calls. They enrolled 203 teens and completed Year 2 interviews with 93%, Year 3 interviews with 91% and Year 4 interviews with 77%, as many of the teens had moved away from their parents’ homes by that point in time.

For “Baltimore Pediatric Eye Disease Study (BPEDS)”, Battelle staff screened adults in over 63,000 Baltimore city and county homes to locate 4,129 eligible children. They then completed over 4,000 enrollment interviews (97%), and over 2,500 children came into a study clinic to have an eye exam (63%).

For “Youth Partners in Care: Depression and Quality Improvement” Battelle followed depressed teenagers for two years. Battelle interviewers were responsible for conducting a 75-minute baseline telephone interview and three 60 minute follow-up interviews administered at 6 month intervals. Cohort maintenance was accomplished through regular postcard mailings in-between the interviewing waves. A total of 461 teens completed the baseline interview and follow-ups were successfully completed with 85% at 6 months, 79% at 12 months, and 79% at 18 months.

Battelle’s data collection capabilities include: telephone interviews (CATI), Face to face interviews, Self-administered web-based surveys, Record abstraction and collection of clinical, biological, and environmental specimens. All the data will meet the FISMA requirement.

Saliva collection:

We will employ the developmental psychobiological approach based on the biological sensitivity to context framework. Core variables of interest are represented below. Consistent with our prior work, we expect that social forces will interact with intrinsic individual differences and health behavior to influence the levels of salivary analytes reflecting activity of the HPA axis, inflammation/immune function and exposure (direct and second hand) to nicotine. Also consistent with our recent work, we will focus on both the levels of analytes with the individual as the unit of analysis, and the concordance or attunement in the analytes levels at the dyadic level.

Social Forces	**Intrinsic Individual Differences**	**Health Behavior**	**Salivary Analytes**
Discrimination	Adult Attachment		Cortisol (Stress)
Social Support	Parenting Stress/Behavior	Smoking	Cotinine (Nicotine exposure)
Access to Services	Maternal Self-Efficacy		CRP (Inflammation)
Financial Strain	Maternal Mental Health		Other stress, inflame/immune markers
Enabling factors			

We propose that a convenience sample of first time mothers recruited at time 1 be invited to submit saliva samples at time 1 and time 2. At time 1 saliva will be collected from the mother while at time 2 saliva will be collected from post partum mothers and from their infant. We will recruit mothers for saliva collection until 65 time 1 mothers and 65 time 2 dyads have successfully returned saliva samples.

Similarly, for the sample of mothers with children age 0-5 recruited for the study, mothers will be invited to submit saliva samples with their child. Again, we will recruit mothers for saliva collection until 65 dyads have successfully returned saliva samples.

Following procedures outlined by Granger and colleagues (2007- Physiology and Behavior), and employed in multiple large scale prospective studies, mothers will donate whole saliva using the passive drool technique. Interviewers will teach mothers the procedure during the home visit. Briefly, they will be asked to imagine they are chewing their favorite food, to move their jaws as if chewing, and to let the saliva generated to pool under their tongue. Next they will gently force the pooling saliva thru a short plastic drinking straw into a 2 mL cryogenic vial. They will be asked to donate 1 mL of saliva which can be accomplished by most adults within 3 minutes. Mothers will collect their children's samples using a commercially available polymer swab (approx. 1 cm x 15 cm) specifically designed for collecting saliva from infants and children. Mothers will be taught how to collect samples using these swabs by the home

interviewer. One end is held by the mother and the other end is placed in the child's mouth--similar to taking an oral temperature. The swab is to be in the child's mouth for 60 seconds.

A total of four samples will be collected per person over a 36 hour period. This is the minimum number of samples required to capture diurnal cortisol rhythms. One sample will be collected at the time of the interview and mothers will be instructed to collect three more samples on the following day on waking, 30 minutes post waking, and either around noon (prior to the major midday meal) or around 6 PM (prior to the major evening meal) depending on the timing of the previous day's collection. Participants will receive a text message or phone call from study staff to remind them to collect the samples. Parents will complete a brief questionnaire for themselves and their child about when they took the samples, when they ate, sleep patterns, stress, medications, and other related questions that might affect the samples. On the day of collection all samples will be stored frozen in the families' home freezer. Following collection, samples will be packed in an insulated shipper with a frozen gel Pak and returned to the Center for Interdisciplinary Salivary Bioscience Research (headed by co-investigator Douglas Granger) by express mail. All collection supplies, packing supplies and express mailers will be provided to the family by study staff.

b. Study duration and number of study visits required of research participants.

Study duration will be from now until data collections occur over an 18 month period. Data analysis will occur for an additional 2 years during which cognitive interviews, and primary data collection with the first time prospective mothers and mothers with young children will be analyzed.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.

Not Applicable.

d. Justification of why participants will not receive routine care or will have current therapy stopped.

Not Applicable. Participants will receive routine health care and medical providers will not know which patients participated and which did not.

e. Justification for inclusion of a placebo or non-treatment group.

Not Applicable.

f. Definition of treatment failure or participant removal criteria.

Not Applicable

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

Participants who enroll, begin the survey but choose not to complete it will be thanked for the service, and will receive prorated remuneration. If the participants are also patients, their care within the Johns Hopkins Healthcare system will not be affected in any way.

5. Inclusion/Exclusion Criteria

a. English Speaking
b. Recruitment Groups

Phase I: 50 African American Mothers

Phase 2:
a. 150 African American and Caucasian first time prospective mothers greater than 20 weeks gestation
b. 250 African American and Caucasian Mothers with children age 0-5

6. Study Statistics

a. Primary and Secondary outcome variables:

Phase I: **Cognitive Interviewing**

- Content validity of the concepts and measures

Phase II: **Primary Data Collection:** Criterion and construct validity of:

- Health Beliefs: Child Development Health Values
- Parent Health Literacy
- Maternal Self Efficacy, Parenting Self-Agency
- Access, Utilization & Quality of Health Services
- Child Health Outcomes

b. Statistical plan including sample size justification and interim data analysis.

Phase I: **Cognitive Interviewing**

Sessions will be taped and transcribed. Content will be assessed using the grounded theory approach with results analyzed using standard qualitative methods.

Phase II: **Primary Data Collection**:
Sample size calculations were based on the agreement of the NVS and & S-TOFHLA:, a primary aim of this study. We have set sample size to make precise estimates of agreement within each of the subgroups of interest and to test for differences in agreement for each of the subgroups as compared with non-Hispanic Whites. Sample size estimates are based on the study of Weiss et al., which found the percent agreement between the NVS and the S-TOFHLA to be 86% among non-Hispanic Whites and 72% among Hispanics. Based on these findings, we have calculated sample size assuming an agreement rate of 70% for each population subgroup of interest and 85% among non-Hispanic Whites.

Estimating Percent Agreement between NVS and S-TOFHLA: For a particular subgroup, a sample of 250 mothers is adequate to construct a 95% confidence interval of $\pm$ 5.5% around a point estimate of 72% agreement between the NVS and the S-TOFHLA. For whites, a sample of 260 is adequate to construct a 95% confidence interval of $\pm$ 4.2% around a point estimate of 86% agreement.

Comparing Percent Agreement across Population Subgroups: A sample of 250 from a population sub-group of interest and a sample of 260 non-Hispanic Whites yields a power 97% to detect a difference in percent agreement given population subgroup levels of agreement of 72% vs. 86% and a two-tailed alpha of 0.05.

Stability of health literacy, discrimination, and parenting self-efficacy measures: Of the 150 first time prospective mothers interviewed during pregnancy (T1) at each site, all will be re-interviewed 6 months later (T2) to assess stability in constructs over time (from prenatal to postnatal period). This will inform appropriate frequency and timing of measurement for the NCS, EOD, and other measures. A sample of 100 from a population sub-group will yield a power of 85% to reject the null hypothesis of 'minimal' agreement between pre- and post-natal administrations of the NVS or S-TOFHLA vs. excellent agreement, with minimal agreement defined as an intraclass correlation coefficient (ICC) of 0.5 and excellent agreement defined as an ICC of 0.7.

Reliability will be assessed in terms of internal consistency (Cronbach alpha). Criterion validity will be determined by calculating the correlation between scores on the NVS and S-TOFHLA and the percent of cases categorized the same by both measures. Age, education level, and NVS will be assessed as predictors of adequate literacy based on the TOFHLA scores by computing their receiver operating characteristic curves. ROC curves will be used to calculate the sensitivity and specificity for selected cutoff scores on the NVS. Stratum-specific likelihood ratios will be calculated for each NVS score. Association of literacy with parenting and access, utilization and quality measures will be assessed.

Saliva Collection:

Our primary hypothesis is that racial/ethnic differences in health disparities will be moderated by salivary analytes reflecting effects of stress on the HPA axis (cortisol) and inflammatory/immune processes. Specifically, women who have low social support, financial and economic disadvantage, and high reported frequency of discrimination, will have higher levels of stress hormones during pregnancy, and those levels will predict post-partum adjustment including higher parental stress, global stress, and post partum depression. A secondary aim of this research, which is exploratory, is to determine which key body systems are impacted by social experience, and how these biomarkers relate to child development and maturation. Therefore, first, saliva will be centrifuged and analyzed for cortisol. We will conduct additional exploratory analyses that would provide us indicators of inflammatory/immune function and tobacco exposure. These measures has been established as important measures of physiological function, however, not all have been evaluated in diverse populations, prenatal to post natal, and among mother/child dyads. Any remaining samples will be destroyed at the end of the study. No other investigators will have access to these samples. This portion of the research will be conducted in collaboration with Douglas Granger, PhD, Professor in the Johns Hopkins School of Nursing, and Director of The Center for Interdisciplinary Salivary Bioscience Research (CISBR). Trained as a developmental psychologist, Dr. Granger is a leading expert on salivary biomarker research, particularly as it relates to child development and well-being.

7. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

There are no medical risks to participating in this study. Some study participants may feel uncomfortable about some of the questions we ask during the interview.

b. Steps taken to minimize the risks.

Participants will be told that their participation is voluntary and they can terminate participation at any time.

c. Plan for reporting unanticipated problems or study deviations.

Any unanticipated problems will be reported to the IRB in accordance with JHMIRB policies. Study deviations will be requested using the changes in research procedures.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

There are no questions which would put the participant at risk for legal problems. This study is covered by the NCS certificate of confidentiality.

e. Financial risks to the participants.

There are no anticipated financial risks to the participant.

8. Benefits

a. Description of the probable benefits for the participant and for society.

There may be no direct benefit to the participant. However, the study could help uncover important new medical knowledge that could benefit children and families in the years to come.

9. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

Phase I study participants will receive $50 cash or giftcard for completion of an interview. Phase II study participants will receive $40 cash or giftcard for each interview. If invited to collect saliva, an additional $20 check or giftcard per person ($20 for mother, $20 for child) will be mailed to them after saliva is received at the Johns Hopkins lab (CISBR).

10. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

There are no costs to the patient for participation in the study. There are no drugs or substances involved in this protocol.

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