Name	Description	Version
Sanders.JHS CTO APPLICATION FORM new fees enforced 10-1-09.acceptedchanges.doc		0.01

NOTE: The Jackson Clinical Trials Office Application Form is available from the Jackson Clinical Research Review Committee page.

4. Description of Study

Study Protocol

4.1. * **Abstract and Specific Aims**

Include a brief summary of the significance, purpose or research question, specific aims, and risks/benefits. Specific aims include hypotheses you will investigate.

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 purpose of this NCS 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 inclusion in the NCS. This formative study will involve 4 other NCS sites (UCLA, Johns Hopkins University, UHawaii, UCIrvine) who will be recruiting patients.

At the University of Miami and in the South Florida community, 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 four 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 of mental health, physical health, and allostatic load to accurately examine health disparities with health literacy as potential mediator of poor health outcomes.

4.2. * **Research Background**

Provide background and previous studies supporting the study rationale. Include a brief summary of existing knowledge relevant to the research. Explain how the research may contribute to the advancement of knowledge.

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. 1 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. 2 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.3

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.4,5 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.6

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 Agency7, Maternal Self-Efficacy (Titi & Gelfand, 10 items, alpha =.86) and parenting behaviors expected and not expected to be associated with health literacy to assess subtypes of construct validity; convergent and discriminant validity.8

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. We will also utilize the Parents' Perceptions of Primary Care (P3C) measure, a brief, practical, reliable, and valid parent report instrument (23 items, alpha=.95 English and Spanish) related to quality of services.9

4.3. **If you have cited references above, please attach a bibliography, including title, full author list, journal, date and pages. This bibliography should include only those articles referenced above.**

Name	Description	Version
References.doc		0.01

4a. Description of Study (cont'd)

Rationale and Methodology

4.4. * **In non-technical, lay language, describe the study design and all study procedures, in order of sequence and timing. Include length of subject participation, what tasks are involved in the study, what tests or procedures subjects will be asked to complete or undergo, specific measures to be used, etc. If applicable, include frequency of visits, duration of visits, and study procedure calendar.**

Phase I: Cognitive Interviewing
Twenty women with children 0-5 years will be recruited. Each participant will be asked to complete a structured interview, which will include discussion of specific items being considered for the larger study in Phase II. Verbal probing will be utilized to delve into the associated cognitive and socio-cultural processes associated with each item, as well as the respondent's advice on how to make these items more clear and more relevant. In addition, participants will provide input about the appropriate approach to recruting and retaining community members in the field, issues that may be missed by the measures, and format of survey delivery (in-person interview, computer-tablet administered formats, and combinations thereof).

Phase II: Structured Interviews
Two groups of women will be recruited from for this larger phase:
1. First time prospective mothers greater than 20 weeks gestation, who will be interviewed during pregnancy (T1) and 6 months later (T2); and
2. Mothers/guardians with children age 0-5 years, who will be interviewed at one time only.

After obtaining informed consent, the research assistant (RA) will help the respondent complete the structured interview. Most of the interview will be a computer assisted personal interview (CAPI), with the RA asking questions and entering most answers into the computer, but with some components utilizing audio computer assisted self interviewing (audio-CASI).

Participants will be asked to provide demographic data such as race/ethnicity, perception of socioeconomic status (SES), geography, urban/rural status of community and education level. Participants will be administered the Newest Vital Sign (NVS) health literacy instrument, S-TOFHLA, a

brief reading comprehension measure (Woodcock-Johnson and Woodcock-Munoz subscales), the Experiences of Discrimination (EOD) Scale, Short Acculturation Scale for Hispanics, Social Support Instrument, Other brief, validated scales will include those measuring parenting self-efficacy, maternal and child health access, subjective social status, acculturation, parenting attachment style Questionnaire, knowledge of infant development, and Parent's Perceptions of Primary Care (P3C).

4.4.A. **Standard Measures:** Click the "Add" button to open the search window, then click the "Find" button to browse and select measures.

Name of Measure	Brief Description	Type of Measure
STOFHLA	Short Test of Functional Health Literacy in Adults	Neuropsychological/Memory Tests/Daily Functioning

NOTE: A copy of the first page of each standard measure is provided in the Library of Standard Measures for verification. Ensure that the version being used in this study is the same as the version that has been selected.

Upload any questionnaires and/or assessment tools to be used that are not listed above:

Name	Description	Version
05_krieger_et_al_EOD_instructions+ssm.pdf	for Structured Interview	0.02
Abbreviated_Multidimensional_Acculturation_Scale-MANUAL.doc	for Structured Interview	0.02
Attachment Style Questionnaire.docx	for Structured Interview	0.03
Cognitive_Interview_11 29.10.b'more group edits - MET_IRB Final.docx	Cognitive Interview Script	0.02
Collective Efficacy Measure Four Item Scale.docx	for Structured Interview	0.02
NVS_Eng.pdf	for both Cognitive and Structured Interviews	0.02
NVS_Label_Eng.pdf	for both Cognitive and Structured Interviews	0.03
T1 First Time Mother Interview 12-7-10 no tracks.doc	Structured Interview -- Main	0.02
WoodcockJohnson.Achievement.9_10.pdf	for Structured Interview	0.02

4.5. **Identify and distinguish between those procedures that are standard treatment versus those that are experimental/research-specific.**

☑ **Not applicable**

4.6. **Describe any therapeutic alternatives that may exist for the study population.**
☑ **Not applicable**

4b. Description of Study (cont'd)

Risk/Benefit Assessment

4.7. * **Describe the nature, degree, and if available, expected frequency of all potential economic/financial, legal, physical, psychological, social or other risks to which research participants may be exposed as a result of their participation in this research. If applicable, please describe the risk of investigational agents or devices (side effects).**
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. They will be told participation is voluntary and they do not have to answer specific questions. ? Disclosure of maternal depression.

There are no questions which would put the participant at risk for legal problems.

There are no anticipated financial risks to the participant.

4.8. * **Are there potential direct benefits of this research to the subjects?**
○ Yes ◉ **No**

4.8.A. **If *yes*, provide a description of the potential direct benefits and indicate if all, or only some, of the subject groups may derive this potential benefit.**

4.9. * **Are there potential benefits of this research to society?**
◉ **Yes** ○ No

4.9.A. * **Please explain:**
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.

4.10. * **Explain why the risk/benefit ratio supports conducting this research.**
The potential benefits to society include a better understanding of how parent literacy, experiences of discrimination, and social support moderates perinatal and early childhood health outcomes. This outweighs the negligible risks associated with individual participation in the interviews, surveys, and brief cognitive tests necessary to obtain this information.

4c. Description of Study (cont'd)

Data

4.11. * **Describe follow-up, data storage methods, data security, authorized access to records and record retention, including site name and address.**
A subject log (with Personal Identifiable Information) will be maintained to enable our Research Assistants to contact participants to schedule their baseline and (for a subsample of 200 subjects) their follow-up interview at 6 months. This subject log -- which by necessity will contain contact information in the form of home and mobile phone numbers and home addresses -- will be kept in a locked drawer in the locked office in the locked suite of offices in the Division of Pediatric Clinical Research, which is accessible only by security ID card.

Digital audiotapes recorded (as well as their transcribed texts) for the Cognitive Interviews will be maintained on a secure desktop computer in the same office.

For each participant in the Structured Interviews, we will collect pen-and-paper responses to some of the brief cognitive tests (STOFHLA, NVS, and Woodcock/Johnson), which will be stored in a locked file cabinet in the same office.

All other electronic data will be sent directly from a secure tablet PC entry system to a secure data warehouse at Battelle -- the world's largest, independent research and development organization. For this study, Battelle is developing a specific, secure data storage system.

Before data collection will begin, we will need to obtain data security clearance from the US Government's Federal Information Security Management Agency (FISMA).

4.12. * **Support the study validity by describing the statistical design, including quantitative and qualitative methods used to analyze data.**
The Primary and Secondary outcome variables are the following:
• Health Beliefs: Child Development Health Values
• Parent Health Literacy (NVS and STOFHLA)
• Parenting Behavior: Maternal Self Efficacy, Parenting Self-Agency
• Utilization of Health Services
• Access & Quality of Health Services
• Child Health Outcomes

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 + 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 + 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.
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.

Data Analysis
Stability of health literacy, discrimination, and parenting self-efficacy measures: Of the 150 first time prospective mothers interviewed during pregnancy (T1) 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.

Privacy/Confidentiality Agreements

4.13. **Describe any privacy agreements or certificates of confidentiality, if applicable.**
n/a

4d. Description of Study (cont'd)

Deception

4.14. * **Is the use of deception part of the study design?**
○ Yes ◉ **No**

If *yes*, please answer the following 3 questions:

4.14.A. **Describe in detail the nature of the deception and explain why this is necessary for the research.**

4.14.B. **State how, when, and by whom the research subjects will be debriefed.**

4.14.C. **Upload a copy of the debriefing script.**

5. Study Participants

Per 45 CFR 46, human subjects (participants) means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual; or
2. identifiable private information (i.e. pathological specimens, medical records, etc.)

5.1. * **Participant Age:**

	Check all that apply	Notes
☐	0-6	*Parent Permission/Consent required for each participant*
☐	7-17	*Parent Permission/Consent & Child Assent required for each participant*
☑	18-65	*Consent required for each participant unless a waiver of consent is approved by the IRB*
☐	65+	*Consent required for each participant unless a waiver of consent is approved by the IRB*

5.2. **For the following questions, please use integers for your responses. For any question that is not applicable, please enter the number *0*.**
(Do not enter commas, decimal points or special characters)

5.2.A. * **Maximum number of subjects in the Protocol to be *screened* at all sites (regardless of PI):**
500

5.2.B. * **Total number of subjects in the Protocol to be *studied* at all sites(regardless of PI):**
360

University of Miami

5.2.C. * **Maximum number of subjects to be *screened* by this PI at *UM*:**
500

* **Maximum number of subjects to be *enrolled* by this PI *at UM*:**
360

* **From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment?**
335

Jackson Health Systems

5.2.D. * **Maximum number of subjects to be *screened* by this PI at *Jackson Health Systems (JHS):***
500

* **Maximum number of subjects to be *enrolled* by this PI *at Jackson Health Systems (JHS)*:**
360

* **From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment)?**
335

Miami VA Medical Center

5.2.E. * **Maximum number of subjects to be *screened* by this PI at *Miami VA Medical Center*:**
0

* **Maximum number of subjects to be *enrolled* by this PI at *Miami VA Medical Center*:**
0

* **From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment)?**
0

5a. Study Populations

5.3. * **Study populations to be included in this study where PI will be conducting research and those sites where the UM IRB will have oversight responsibility:**

Check all that apply	Notes
Normal, healthy volunteers	
Pregnant women/fetuses	Specific Florida statutes apply to prohibit the use of any live fetus or live, premature infant for any type of scientific, research, laboratory or other kind of experimentation except as necessary to protect or preserve the life and health of such fetus or premature infant.

5.3.A. **If *other*, please specify:**

5.3.B. **Describe below any additional safeguards that have been included to protect vulnerable subjects:**

5b. Inclusions/Exclusions

5.4. * **Is the population being enrolled in this study at high risk for incarceration?**
○ Yes ◉ **No**

5.4.A. **If *yes*, will the subjects be withdrawn from the study once they are incarcerated?**
○ Yes ○ No

5.4.A.(i) **If the above answer (question 5.4.A.) is *no*, describe how re-contacting/re-consenting, treatment, and/or follow-up will occur:**

NOTE: *If a subject becomes incarcerated while enrolled in a study, all research interactions and interventions with that subject, and the obtaining of identifiable private information about the subject, must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol.*

If notified that a previously enrolled research subject has become a prisoner, the principal investigator must promptly seek IRB re-review of the protocol in accordance with the requirements of subpart C if the principal investigator wishes to have the prisoner-subject continue to participate in the research. ***In special circumstances in which the principal investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.***

5.5. * **What are the criteria for exclusion of participants from the research?**
1. Males
2. Mothers and expectant mothers younger than 18 years of age

5.6. * **Will any population be systematically excluded in this study?**
○ Yes ◉ **No**

5.6.A. **If *yes*, provide rationale/justification for this exclusion:**

5.7. * **What are the criteria for inclusion of participants in the research?**
English or Spanish Speaking. This is consistent with the National Children's Study inclusion criteria.

As part of an effort to expand the ethnic and cultural diversity in this multi-center study, we will be over-sampling among women of Latino and of Caribbean origin.

5.8. * **Will only one group of individuals be systematically selected and recruited for this study (e.g., welfare patients, racial and/or ethnic minorities, persons confined to institutions or persons determined to be incapacitated)?**
○ Yes ◉ **No**

5.8.A. **If *yes*, please state how this participant group will benefit from the results of the research and provide the reasons and justifications to target this group:**

5c. Research Involving Pregnant Women or Fetuses

Pregnant woman or fetuses may be involved in research if ***ALL*** of the following conditions are met (all items must be justified):

(a) **Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.**

*** Justification:**
This study involves only interview, survey, and brief cognitive (literacy) tests for the study participants, some of whom will be pregnant at the time of study participation.

This study involves no treatment, procedures, or invasive testing.

(b) **The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.**

*** Justification:**
This study involves only interview, survey, and brief cognitive (literacy) tests for the study participants, some of whom will be pregnant at the time of study participation.

This study involves no treatment, procedures, or invasive testing.

(c) **Any risk is the least possible for achieving the objectives of the research.**

*** Justification:**
The study's main risk are the participant's possible feelings of stress, shame, or other negative emotions associated with the more sensitive components of the survey.

The most sensitive survey components include the tests of reading and math ability (NVS, STOFHLA, Woodcock/Johnson) and the survey instruments related to experiences of discrimination.

To minimize these risks, the PIs will insure the following:

1. Each research assistant (RA) will be selected and trained for the skills necessary to reduce the negative emotions associated with these tests and surveys. This includes re-iteration of positive praise during the interview process, strategic breaks, and quick "check-ins" and "debriefs" during the interview process. (The PIs at this site and others have extensive experience with such training and with these specific survey instruments.)

2. The Cognitive Interview itself is designed in large part to minimize these risks during the larger Structured Interview stage. Respondents will be invited to suggest ways to reduce the stress and negative emotions associated with answering the literacy, numeracy, and discrimination questions.

This study involves no treatment, procedures, or invasive testing.

(d) **If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part.**

*** Justification:**
This research is likely to develop imporant biomedical and sociomedical knowledge that cannot be obtained by any other means.

(e) **If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.**

*** Justification:**
The research is primarily of benefit to biomedical, sociomedical, and sociobehavioral research and policy. It holds no direct benefit or risk to the fetus.

(f) **Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.**

*** Justification:**
Though there is no direct benefit or risk to the fetus, each participant will be fully informed (orally and in writing) regarding the purpose and nature of the study.

(g) **For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part.**

*** Justification:**
We will not enrollee participants (pregnant or otherwise) under age 18 years.

(h) **No inducements, monetary or otherwise, will be offered to terminate a pregnancy.**

*** Justification:**
No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

(i) **Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.**

*** Justification:**
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

(j) **Individuals engaged in the research will have no part in determining the viability of a neonate.**

*** Justification:**
Individuals engaged in the research will have no part in determining the viability of a neonate.

6. Subject Recruitment

6.1. *** From what sources or by what methods will subjects be recruited?**

Check all that apply
Flyers/newsletters
Primary physician/physician specialist
Outpatients/clinics
Direct contact
Posters

6.1.A. **If *postings within hospital*, please indicate name of facility:**

6.1.B. **If *emergency room*, please indicate name of facility:**

6.1.C. **If *other*, please specify:**

6a. Subject Recruitment (cont'd)

6.2. * **Provide a step-by-step description of the recruitment procedures used to identify and/or contact prospective participants:**

Phase I: Cognitive Interviewing
Twenty women with children 0-5 years will be recruited to complete cognitive interviews at the BCRI site. 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 Participants will be recruited from UM and JMH out-patient pediatric primary-care and ob-gyn clinics -- through flyers and through listserve announcements to faculty and staff .

To facilitate effective and ethical recruitment that does not interrupt clinical care or community service, we will do the following: (1) PIs and RAS will meet with clinic directors and staff to inform them of the study; (2) as appropriate and permitted, RAs will provide flyers (in English and Spanish) to be posted prominently in each clinic waiting room and exam room; and (3) as appropriate and permitted, RAs will be stationed in waiting rooms to request study participation from interested participants. The RA will ask interested participants to answer a brief set of questions to determine study eligibility and to share their contact information (telephone numbers, email address) to schedule an interview at the most convenient available time and place. The audiotaped interview will be conducted on the UM ?JMH campus.

Phase II: Structured Interview (Primary Data Collection)
Two groups of women will be recruited from obstetric and pediatric primary care sites:
1. First-time prospective mothers greater than 20 weeks gestation, who will be asked to complete 2 interviews, one at baseline (T1) and one 6 months later (T2); N = 150 (expected 17% attrition to 125 by T2);
and
2. Mothers/guardians with children age 0-5 years, who will be asked to complete a single interview; N =190.

UM/JMH campus recruitment sites for this component of the study will be Ob Gyn and prenatal care clinics. Additional community-based recruitment sites will include community-based Ob Gyn clinics, prenatal care clinics, Healthy Start screening sites, and child-care centers. (Letters of agreement pending.)

To facilitate effective and ethical recruitment that does not interrupt clinical care or community service, we will do the following: (1) PIs and RAS will meet with clinic directors and staff to inform them of the study; (2) as appropriate and permitted, RAs will provide flyers (in English and Spanish) to be posted prominently in each clinic waiting room and exam room; and (3) as appropriate and permitted, RAs will be stationed in waiting rooms to request study participation from interested and eligible women.

The RA may ask interested participants to answer a brief set of questions to determine study eligibility and/or to share their contact information (telephone numbers, email address) to schedule an interview at the most convenient available time and place. Some interviews, however, may be conducted at the time of recruitment. The interview will be conducted either on the UM campus (BCRI), at the clinical site, or at the community site.

6.2.A. **Please upload copies of scripts, recruiting materials, and advertisements:**

Name	Description	Version
NCS Flier met.UM.docx		0.01

NOTE: *Any materials that will be given to or seen by potential subjects must be reviewed and approved by the IRB. This includes assessments, instruments, diaries, questionnaires, and all screening and recruitment materials, including advertisements, web postings, letters, and telephone scripts. Only IRB approved versions of these materials may be used during the course of the study.*

6.3. * **What measures will be taken during the recruitment process to safeguard against the potential coercion or the appearance of coercion of participants, particularly vulnerable populations?**

As part of orientation and training for the study -- each RA will be trained to re-iterate at the time of study enrollment that STUDY PARTICIPATION IS NOT REQUIRED and that refusal to enroll or participate will in no way affect the delivery of patient care.