REQUEST FOR OMB CLEARANCE
Child Health Disparities Substudy for the National Children's Study (NICHD)
Phase I: Cognitive Interview Testing of Constructs Needed for Disparities Measurement

Part B only

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B. Collection of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Methods

The following women are eligible for participation in Phase I of the Child Health Disparities Substudy:

- Women of the age of majority (typically, age 18) with children 0-5 years of age

Women who do not have children between the ages of 0 and 5 years and women who are not yet 18 years old will be excluded. Additionally, Study Centers will sample women who self-identify as a specific race or ethnicity.

Participants for this substudy will be recruited as a convenience sample of women attending visits at clinics and hospitals associated with Study Centers or recruited at Women, Infant and Children supplemental food sites, child care sites and other public sites using flyers. Persons demographically similar, but not geographically eligible, to participate in the NCS Vanguard Study will be invited to join. For this substudy, we aim to recruit participants who self-identify as Black or African-American, Spanish-speaking Latina including Central American, Caribbean, and Mexican-American, English-speaking Asian or Pacific Islander. The five participating Study Centers will recruit pre-determined demographic ethnic groups based on local area population. For example, Asian and Pacific Islanders will be recruited in Hawaii. Black or African-American women will be recruited in Maryland. Spanish-speaking Latina women will be recruited in Florida. Spanish-speaking Mexican, Asian, and Caucasian women will be recruited from California. Enrollment will continue until project-specific recruitment targets have been met; please see Table A1 in section A.2. Invitations to join the substudy will clearly indicate the separate and distinct nature of NCS substudies from the NCS Vanguard Study. Invited participants will be informed that their participation in NCS substudies is voluntary.

B.2 Procedures for the Collection of Information

Phase 1 of the Child Health Disparities Substudy will include a cognitive interview. Participants will be recruited by flyers and will be asked screener questions from the Cognitive Interview Screener to determine eligibility. Screening will primarily take place over the phone but may also take place in person. Participant eligibility is based on age (18 and older), sex (female), child age (0-5 years), race/ethnicity (dependent on each site's target population goals). Cognitive interviews will occur one time with consented participants. Once consented into the study, participants will be asked to participate in a 60-75 minute interview following the style of cognitive interviewing. Cognitive interviewing focuses on the cognitive processes that respondents use to answer questions. Cognitive interviews will be conducted with a total of 60 women across all participating Study Centers. 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, education, and stress. Verbal probes will be used to delve into the associated cognitive and sociocultural processes. In addition, participants will be able to provide input on the appropriate approach to community members in the field, issues that may be missed by the measures, and the format of data collection. Responses

from the cognitive interview will be analyzed by using the grounded theory method (explained A.16), and the results will inform the adaptation or translation processes for further refining instrumentation to be used for the larger data collection effort.

The Cognitive Interviewing Guide is structured around core areas of interest: health literacy, experiences of discrimination, and experiences of unfair treatment, stress, and educational attainment. For health literacy, the participants will be asked to complete the Newest Vital Sign™ (NVS) instrument and then respond to it based on interviewer questions and prompts. Following that, participants will be asked questions from the Krieger Experiences of Discrimination and Williams Response to Unfair Treatment measures and then asked to respond to them. Interviewers will ask questions like "What did you have to think about in order to answer that question?" and "Tell me more about why you chose that response." Next, participants will answer questions about stress, perceived stress, and parenting stress. The stress questions are open-ended and are original content developed by the study team. Participants will also be asked to give their opinions on different possible modalities of interviewing, and the collection of demographic data such as education level.

Questionnaires: Cognitive interviews will be conducted by a trained interviewer in a private space. Interviews are audio-recorded. The interviewer will ask questions and probe for in-depth responses. The interview guide presents participants with validated instruments and then elicits their responses to those instruments.

Questions from the following validated instruments will be used in the cognitive interview:

Health Literacy

Newest Vital Sign™ (6 questions total; 1-4 combined numeracy/literacy, 5-6 literacy/comprehension) (NVS; Weiss et al., 2005): The NVS is a nutrition label that is accompanied by 6 questions and requires 3 minutes for administration. It is reliable (Cronbach α >0.76 in English) and correlates with the Shortened Test of Functional Health Literacy in Adults (S-TOFHLA) (Weiss et al 2005). The Test of Functional Health Literacy in Adults (TOFHLA) has strong psychometrics, is widely used, and is available in English and Spanish. It uses realistic health care materials (ex: pre-op instructions) to measure functional health literacy in adults. However, the measure is lengthy with the full version requiring 18-22 minutes and the short version 7-10 minutes. The NVS is a relatively new rapid literacy assessment instrument. It is a 6-item test based on the ability to read and apply information for a nutrition label. This measure assesses reading and numeracy skills. It has been validated against the TOFHLA in English and Spanish and was found to be a reliable and accurate measure of literacy with high sensitivity for detecting limited literacy. However, psychometric properties of the Spanish version were not as good as those of the English version possibly because of greater heterogeneity of language and culture among Spanish-speaking patients from Mexico, Central America and South America. Further testing of this instrument in Spanish-speaking populations and in other diverse populations is needed, especially in mothers of young children. All six questions of the NVS will be administered. After use of the NVS, participants will be asked to respond as to how easy or difficult they found the test. They will be asked about their

familiarity with other food labels by being shown an example other than the one provided by the NVS instrument.

Discrimination and Unfair Treatment

This study will make use of the Krieger and Williams measures of discrimination and unfair treatment. Nancy Krieger validated her measure in 2005 in a diverse population of Black, Latino, and White Americans. Since then, it has become a standard measure of discrimination and racism in health research. The second is the "Every Day discrimination Measure" developed by David Williams at Harvard. This 'everyday' measure comes from work done by Philomena Essed, author of several books on experiences of everyday racism. Essed's measures were later validated by David Williams in the Detroit Area Study in 1995. The Williams measure is now widely used in health research. When combined, the Krieger and Williams measures are a powerful tool for capturing experiences of discrimination, and particularly, racism. They capture different but related experiences so they can complement each other or stand alone. The Krieger measure focuses on an "ever in lifetime" scale and addresses how individuals react to these events. The Williams measure can get more specific in terms of how a person was discriminated against and whether it was a racial reason or something else.

Krieger Experiences of Discrimination (EOD) (11 items, 1-2 response to unfair treatment, 3-11, occurrences of discrimination and frequency) (Krieger N, Smith K, Naishadham D, et.al. Social Science & Medicine, 61 (2—5): 1576-1596. The EOD is a valid and reliable (Cronbach's alpha 0.74 or greater) short self-report measure of experiences of racial discrimination. The measure has been used to demonstrate experiences of discrimination amongst African American and Latino adults and has been associated with psychological distress and adverse health risks such as cigarette smoking. The full scale contains subsections on Response to Unfair Treatment, Discrimination, Worry Questions, Global Questions, Filed Complaint. The cognitive interview will use the Response to Unfair Treatment and Discrimination Domains only (11 items, 1-2 response to unfair treatment, 3-11 occurrences of discrimination and frequency).

Williams Everyday Measure of Discrimination (21 Items, 1-9 Major Discrimination 10-19 day-to-day unfair treatment/experiences of unfair treatment, 20, reason for experiences, 21, response to experiences) (Williams, D.R., Yu, Y., Jackson, J.S., and Anderson, N.B. Journal of Health Psychology. 1997; 2(3):335-351) is a scale which captures lifetime experiences of unfair treatment , day-to-day unfair treatment, and responses to unfair treatment. The measure was first used during a study of racial differences in physical and mental health. Validity and reliability were further evaluated in two subsequent studies. (Krieger N, Smith K, Naishadham D, et.al. Social Science & Medicine, 61 (2—5): 1576-1596, Taylor T.R. International Journal of Behavioral Medicine. 2004; 11:88–94. The full scale (often used with the Krieger Experiences of Discrimination) contains domains: Major discrimination, Day-to-day unfair treatment, and Response to unfair treatment. The Cognitive Interview will use the domain of Day-to-day unfair treatment only (not the major discrimination portion) (12 items, 1-10 experiences of unfair treatment, 11 reason for experiences, 12 response to experiences). These measures capture different but related experiences. Use of both instruments would be too lengthy for the NCS; thus, this study aims to find the most effective and efficient method for measuring experiences

of discrimination. We expect to be able to recommend the use of either one measure over the other or possibly a combination of parts of each. Furthermore, while there has been some validation of these measures across diverse populations, assessing validity in across even more populations of mothers will be important for the NCS. And finally, the study team inserted items/options related to discrimination or unfair treatment specifically experienced while obtaining medical care that are not present in the original instruments which we hope to be illuminating.

Educational Attainment

The question on educational attainment included in the cognitive interview uses common US educational categories as recommended by the US Census Bureau[1]. By including this question in the cognitive interview, investigators hope to gauge participant response to the format – for example, by asking them if they found it easy or hard, too short or too long, etc and make recommendations on the appropriateness of the question after the data has been collected and analyzed. Education level is often used as a proxy for socioeconomic status and sometimes correlated with health literacy. However, standard measures of years of schooling or graduation from high school or college may have different meanings or equivalence for immigrants from other countries.

Stress

The stress section of the cognitive interview does not contain any standard instruments but rather common questions from the domain of stress asked in a qualitative manner. This section was designed to gather information on participants' thoughts and reactions when asked about the domain of stress. Though research has shown stress level to be correlated with health status and has shown stress to be correlated with experiences of discrimination, little work has been done to fully investigate the connection between stress and heath disparities. By including stress as a domain in the Cognitive Interview and larger Disparities study investigators hope to uncover this connection and better understand its effects on patient health.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Since women will be recruited for cognitive interviews until a target of 60 participants that meet the expected race and ethnicity mix will be reached, this Phase I substudy does not require efforts to maximize response rates other than ensuring an efficient identification of potentially eligible women. Study staff will post flyers and canvass the recruitment sites such as WIC (Women, Infant and Children supplemental food sites), child care sites and other public sites to identify and screen potentially eligible women until the target number of women are successfully recruited for cognitive interview testing.

[1] See the US Census Bureau "Educational Attainment" https://www.census.gov/hhes/socdemo/education/about/index.html

Specific methods utilized to maximize efficient recruitment and cooperation includes:

- A national in-person training for all Research Assistants to ensure full understanding and compliance of participant recruitment and survey administration;
- Multiple trainings held with each Study Center on FISMA compliance and entering data into the centrally housed database to ensure high quality data submission;
- Bi-weekly conference calls with all study Principal Investigators and Research Assistants to provide a forum of discussion and updates;
- The development of a Manual of Operations to detail all aspects of the study including recruitment, survey administration and entering data into the database;
- A clear and concise explanation of all study requirements is given to potential participants prior to signing a consent form, to ensure they are knowledgeable about what participation entails;
- Reminder phone calls are made the night before study interviews to remind participants;
- Incentives for participant time that is provided

B.4 Tests of Procedures or Methods to be Undertaken

We have pilot tested the one-time cognitive interviews with nine mother**s** with children aged 0-5, with an average length of 50 minutes per cognitive interview. Pilot testing was done with women in the target population from the community around the study site. Pilot testing followed the protocol developed for the Cognitive Interviews. Participants were recruited, consented and compensated for their time according to protocol and IRB standards (though this was pre-OMB approval, each site was required to have local IRB approval before piloting). Piloting focused on general understandability and length of time for completion. One important discovery the study team made through pilot testing related to prompting and encouraging participants to speak in detail. With our original study guide and training for interviewers, we had instructions to 'probe' participants after certain responses; however, upon listening to the audio of several pilot interviews, the study team realized they were not getting the more detailed answers desired. The pilot testing also brought to light differences across sites. For example, pilot tests from the Hawaii site revealed different experiences of discrimination than the pilot tests in Maryland. This underscored the importance of the multi-state study design in testing for validity of scales across diverse populations. Piloting also confirmed that many women were eager to participate in this substudy. As a result of the pilot interviews and evaluation of studies with similar activities, we have learned that our recruitment and retention strategies, coupled with our study protocol and well-established study network, allow us to expect that we will successfully enroll and consent women for this substudy.

We will utilize the following strategies for quality improvement to ensure that our collaboration learns from all Study Centers' experiences regarding recruitment and administration of study protocol.

- Biweekly conference calls with study Principal Investigators, Project Coordinators and Research Assistants at all Study Centers to provide a forum of discussion and updates;

- Feedback Form that Research Assistants complete after each interview, which reports any challenges encountered with the study protocol and recommendations for improvement;
- Study Coordinator maintains communication across all Study Centers and oversees the Manual of Operations, training of all research staff across Study Centers and maintenance of protocols.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Each formative research project team is staffed with appropriate statistical expertise and is supported by a designated NCS Program Office subject matter expert and NCS statistical and field support staffs. Additionally, study centers continue to consult with federal agency representatives, advisory, and research groups, as well as individuals from statistical agencies on issues related to the NCS, including formative research and pilot testing.