

Section A Study Overview

The goal of the study is to develop age-specific short forms of the Bayley Scales of Infant and Toddler Development-Third Edition ("Bayley-3"), a standardized assessment of young children's cognitive, language and motor development. Short forms will be developed for the 6-month, 12-month, 18-month, 24-month and 36-month ages. We have conducted psychometric analyses to select the items to include in the short form, reformulate the administration and scoring procedures for maximum feasibility in the field, obtain pilot data; we now propose to administer the Bayley Short Form and conduct further psychometric analyses with these data to ensure that the short form is the psychometric equivalent of the full form. Accordingly, we will recruit 300 young children (and their parents) between the ages of about 4 months and 44 months. Depending on the results, we may request to recruit additional children. Exclusion criteria include children with medical diagnoses, children with a developmental delay, or children from households in which English is not the primary language spoken in the home.

Informed consent will be obtained from parents or legally authorized representatives (LARs) for their child's participation. Parents also will be asked to provide standard demographic information about the child (e.g., gender, age, household composition and income) during a short (approximately five minutes) phone screener. The demographic information will be used in the psychometric analyses to rule out differential item functioning and differential test functioning potentially associated with demographic factors.

The Bayley-3 items will be administered by Westat staff who have received training on the procedures and who have educational backgrounds in child development, developmental psychology, and school psychology. The estimated time for the child's participation is 35 to 70 minutes, depending on the child's age.

IRB of Record: Westat is subcontractor to University of Texas Health Science Center at San Antonio (UTHSCSA) for this activity. For the Human Subjects activities that will be done at Westat facilities, Westat will be the IRB of record. However, each site will submit to their local IRB for approval of a protocol describing these tasks relating to their particular involvement in the project, as appropriate. Contact with potential participants will not occur until all relevant IRB clearances have been obtained.

Section B Informed Consent Process

The researchers conducting The Bayley assessment with children will obtain written informed consent from the parent or LAR before the assessment process begins. Details about The Bayley will be provided so that parents or LARs can decide in a free and informed manner whether they want their child to participate. Researchers will clarify any questions that parents have about the study and provide a written copy of the Informed consent for the parent to take home in case they have future questions about the study or their rights.

Section C Risks

Risks to children participating in The Bayley are minimal, and the procedures involve no pain. Although some children may become upset or may cry during the Bayley, this is normal for children at this stage of development. If a child becomes distressed and does not want to continue, we will stop The Bayley. The risks are minimal compared to the indirect benefits of participating in the study.

Section D Benefits

Although there are no direct benefits for participation, there are indirect benefits. Parents and children will help us develop a new tool that shows what and how children learn. Their participation will contribute to the development of an efficient tool that can be used to study the well-being of the nation's children in future nationwide studies. Frequently, parents also report that they enjoy watching their children learn and demonstrate new skills.

Section E Confidentiality, Data Security, and Destruction Procedures

Data will be recorded on hard copy Bayley forms. Individual child names will not be entered on The Bayley forms; data will not use direct identifiers but instead use code numbers corresponding to participants. The crosswalk of these direct identifiers and ID codes will be kept in a locked cabinet; access will be limited to those whose role in the project requires it. The results of the research will be presented in aggregate. All NCS Data Access and Confidentiality policies will be followed as described in the NCS Data Access and Confidentiality manual.

All forms related to this study will be stored in locked cabinets within locked offices that are accessible only by the specific staff members trained on The Bayley. Electronic data will be kept at Westat for analysis. Once analyses are completed, all hard copies of Bayley forms and an electronic copy of the data will be returned to UTHSCSA. NCS data handling and destruction procedures will be followed.