

NCS Formative Research Template for OIRA Clearance

TO BE COMPLETED BY STUDY CENTER:

LOI #:

LOI - - - -

Title of Formative Research: [Bayley-3 Short Form for the National Children's Study](#)

Participating Institutions: CHOP, UTHSCSA, University of Washington

Recruitment Study Arms: Enhanced Household; Two-Tier High-Low

SME:

COTR: Eric Lorenzo and Carl Hill

Purpose of the Study: [The NCS formative research project LOI2-QUEX-5 will explore the feasibility, acceptability, and cost of age-specific short forms of the Bayley Scales of Infant and Toddler Development Third Edition \(BSF-3\), a standardized assessment of young children's cognitive, language, and motor development for use at child age 6-, 12-, 18-, 24-, and 36 months.](#)

Benefit to NCS Vanguard or Main Study: [The project tests the feasibility, acceptability, and cost of short forms of the Bayley-3, which will inform the design of the NCS Main Study. If scientifically robust, efficiencies in field administration, reducing burden, child fatigue, and costs would warrant testing within the Vanguard and potentially Main Study.](#)

Study Design: [We have conducted psychometric analyses to identify items to be included in the BSF-3, and have reformulated the administration and scoring procedures for maximum feasibility in the field. We have tested the BSF-3 with nine children within the proposed age-ranges of assessment, and have conducted further psychometric analyses with these data to ensure that the BSF-3 is the psychometric equivalent of the full form. We now propose to recruit a convenience sample of 300 participants who are demographically similar to NCS Vanguard Study participants, but who are not geographically eligible to participate in the Vanguard Study, into this formative research study \(see attached Exemplar Recruitment Flyer\). Enrollment will continue until recruitment targets have been met. Parents responding to the flyer will be asked to provide limited demographic information about the child \(for example, sex of child age, household composition, and socio-economic status\) during a short 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 estimated time for the child's participation is 50 minutes, on average.](#)

Target Respondents: [These participants will be demographically similar to NCS Vanguard Study participants, but will be recruited outside of that cohort, given the child age ranges needed to test the short form. Participants will be English-speaking children who do not have any reported medical problems.](#)

Method of Recruiting: [Flyers will advertise call-in numbers that potential participants can use to contact project coordinators.](#)

***Confidentiality:** [Study Centers must abide by the terms of their Data Use Agreement, which should reference all formative research efforts involving the collection or management of NCS restricted-use data. All participating Study Centers will have approved Data Use Agreements and Security Plans prior to launch.](#)

***IRB Approval:** [Local IRB clearance for this activity has been obtained by all participating Study Centers; please see attached IRB approval letters.](#)

Remuneration: [Consistent with the approved NCS Vanguard Study Phase 2 incentive structure, we propose to offer a \\$25 monetary incentive for each participant contact of this formative research project, up to 1 hour of information collection activity.](#)

Sensitive Questions: [We will not ask sensitive questions as a component of this study.](#)

* To be completed before project proposal is submitted for OIRA clearance.

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Proposed Project Schedule: We will begin this project upon receipt of all regulatory approvals.

Data Collection Burden:

	Burden Hours	# of Respondents	Total
Telephone Screener	.08	300	25
Consent	.17	300	50
BSF-3	.83	300	250
Total Respondent Burden Hours			324
Proposed Monetary Incentive		\$25	300
			\$7,500

Please check here after ensuring that all calculations have been verified

Estimated Costs: Staff Hours: 648 hours.
Supervisor Hours: 162 hours.

Attachments: Exemplar Flyer, Exemplar Consent, Telephone Screener, Assessment Description, Exemplar IRB Protocol, IRB Approval Letters. Note: The flyer and consent will be customized for each participating study center and target population, as appropriate, and approved by the local IRB prior to use.

Please check here after ensuring that the OMB #: 0925-XXXX and Expiration Date: XX/XX/XXXX date have been inserted as first-page headers on each proposed instrument.

Please check here after ensuring that the following OMB burden statement has been inserted as a first-page footer on each proposed instrument.

Public reporting burden for this collection of information is estimated to average [SC insert estimated response time] minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0590*). Do not return the completed form to this address.

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Appendix 1. NCS Incentives, by Study Activity and Impact on Participants, Stage 1 (Approved by OMB 7/23/10)

Data Collection Activity Characteristics	Initial NCS Vanguard Study	NCS Recruitment Substudy
Time for encounter	3 hours	0.5 to 1 hour
Sensitivity of questions	Sensitive, including sexual activity	Few sensitive questions
Physical measures	Yes	No
Environmental specimens	Yes	No
Biospecimens	Yes	No
Participant observation	Yes	No
Monetary incentive, per visit	\$100*	\$25
Non-monetary incentives (tote bags, post its, key chains, etc.)	<u>In addition to the monetary incentive</u> , non-monetary incentives valued at \$25 or less may be offered to participants	<u>As an alternative to the monetary incentive</u> , NCS logo gifts valued at \$25 or less may be offered to the participants in lieu of cash or local incentives not exceeding \$25 in value and deemed non-coercive by local IRBs