

Parental Permission for The Bayley Child Development Study Parents of Children 4- to 44-Months Old

You are being asked to allow your child to participate in the research study titled “Bayley Scales of Infant and Toddler Development-Third Edition (Bayley-3 or “The Bayley” for short). The Bayley is a standardized measure of children’s developmental status, including thinking, learning, communication, and motor development. The Bayley was developed to measure children’s skills at different stages of their development and has been widely used for several decades. The purpose of this study is to develop a short form of The Bayley that can be used in large-scale studies of children’s developmental status. It will be administered by Westat staff who have received training on The Bayley procedures.

You will be present during all interactions with your child. Details about The Bayley are provided below so that you can decide in a free and informed manner whether you want your child to participate. The participation of your child in this study is voluntary. Refusal to participate will result in no penalty or loss of benefit to you or your child. You will be given a copy of this consent form. If you have any questions at any time, please ask the individual conducting The Bayley or the staff members named below.

What is the purpose of this assessment?

The purpose of this study is to develop a short form of The Bayley. The following skills are explored:

- Cognition: how children think, learn, and solve problems
- Communication: how children understand gestures and words and how they acquire and use language
- Motor: fine motor skills, such as grasping, and gross motor skills such as crawling, walking, etc.

We would also like to include the basic demographic information about your family (e.g., parent education, number of older/younger children) that you provided during the initial phone call. That information will help us understand our results better.

How many children will participate in this study?

Initially, we will include approximately 300 children for this study. Depending on the results, we may need to ask for the participation of more children.

What is involved in this study and how long will our participation be?

Public reporting burden for this collection of information is estimated to average 10 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 (0925-0593). Do not return the completed form to this address.

The study can be completed in a single session. The Bayley will take about 35 to 70 minutes depending on your child's age, during which the researcher will interact with your child performing different activities to explore his/her cognitive, communication and motor skills.

Are there any reasons your child should not participate?

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

What are the possible benefits?

Although there are no direct benefits for you or your child's participation, there are indirect benefits. You and your child will help us develop a new tool that shows what and how children learn. You and your child's 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.

If you choose not to allow your child to participate, what other options do you have?

Your child does not have to participate in The Bayley. There are no alternatives to The Bayley: your child's participation is entirely your choice.

Can I withdraw my child's participation in this study?

Yes, you may withdraw your child's participation at any time without penalty. You still will receive compensation if your child does not complete The Bayley.

How will your family's confidentiality be protected?

Your participation in this study and the results will not be shared with anyone other than the staff members participating in this research project who have pledged to keep your participation confidential. Your child's name will not be entered on The Bayley forms; data files will use unique ID numbers and your name and contact information will be kept separate from your responses to study questions. All forms related to this study will be stored in locked cabinets within locked offices that are accessible only by the specific staff members who have pledged confidentiality. The results of the research will be presented by combining information of all study participants.

Will you or your child be paid for participating or will it cost you to participate?

Your child can participate in this study at no cost to you. Additionally, you will receive \$25 to thank you for participating in this study.

What if you have questions about this study?

If you have further questions about this study, please ask the staff member working with your child. If you have questions about the purpose and content of this study, please contact the study's Principal Investigator, Carol Andreassen, PhD, at (310) 610-4838. If you have any questions about

your rights as a research participant or have concerns about your participation, please contact the Westat IRB administrator, Sharon Zack, at (301) 610-8828

Parent's Permission:

I have read the information provided above. I have been given the opportunity to ask questions and these questions have been answered. I voluntarily agree to allow my child to participate in this study.

Printed Name of Child

Signature of Parent/Legally Authorized Representative

Date

Printed Name of Parent/Legally Authorized Representative

Person Obtaining Consent/Parental Permission:

Signature of Person Obtaining Consent/ Parental Permission

Date

Printed Name of Person Obtaining Consent/Parental Permission