

Form Approved
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Exp. Date: xx/xx/xxxx

**Attachments 8c-8d-8e-8f-8g: Review of Enrollment and Informed Consent or Assent,
In-person Assessment of Intellectual Abilities**

Public reporting burden of this collection of information is estimated to average 90 minutes, 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 CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0010).

Study to Explore Early Development (SEED) Follow-up Studies

Informed Consent Form for Parents and Legal Guardians

Thank you for your recent participation in the SEED Follow-up Studies. You are being invited to be in another part of this research study. The SEED Follow-up Studies are funded by the Centers for Disease Control and Prevention (CDC). CDC is a federal agency that works to improve the health and safety of people. CDC is working with research partners across the country to conduct the study. Your participation will help us learn how we can support different types of children and families as they grow older.

What is the purpose of the study?

The SEED Follow-up Studies look at changes that happen between the preschool years and adolescence and young adulthood. Some of the changes we are interested in are health, healthcare, safety, services, and treatments. Another is how learning abilities change over time. We are inviting you to this part of the study on changes in learning abilities now.

One of our goals is to better support people with autism and other developmental delays or disabilities as they grow older. To reach our goals, we need different types of people and families to participate in the study.

Why am I being asked to be in this part of the study?

You are being invited to take part in this study because you participated in SEED in the past. Specifically, your child completed an evaluation of early learning abilities between 2 and 5 years of age. Recently, you also completed a survey about your child's current health and development.

What will my child have to do to be in this part of the study?

Your child will be asked to complete an evaluation of learning abilities. This involves answering questions and completing activities like puzzles. It also involves comparing pictures presented on an iPad. The evaluation will take up to 1.5 hours. Your child can stop the evaluation at any time without penalty.

Why should my child be in this part of the study?

There is no personal benefit for being in this part of the study. Your child's participation will help us learn more about how learning abilities change over time. This information may be used to help people with autism and other developmental delays and disabilities. One way to help people with autism and other developmental delays and disabilities is to offer better services and treatments.

Are there any risks involved with this part of the study?

There is little risk involved with the evaluation. Your child may feel nervous working with a new person. The person who gives the evaluation will make sure your child is comfortable before testing begins. Your child may become tired during the evaluation. Short breaks will be given as needed. You will receive written results from the evaluation. You may get feedback that is unexpected and/or shows

below average skills. We will tell you how to contact someone if you have questions. You are also encouraged to share results with your healthcare provider.

Is this going to cost me anything?

There are no costs for being in this part of the study.

Will I get anything after the evaluation?

You will receive a \$45 gift card for being in this part of the study. The gift card is to thank you for your participation. It can also be used to cover travel expenses.

You will receive written results within one month of the evaluation. The letter will explain each test given to your child. It will explain your child's scores on each test. It will tell you how your child performed compared to other people the same age. We encourage you to share these results with your healthcare provider.

We will send you a study newsletter up to two times per year. It will be emailed to you, or you can find it on our website at [SEED Newsletter | CDC](#). It will tell you what we are learning from the study.

Will my child's information I give be kept confidential?

Any information that identifies your child will be kept confidential unless otherwise required by law. A study ID will be assigned to evaluation results. Only people working on the study will be able to link study IDs to names. The link will be kept on a password-protected computer. Evaluation forms will be kept in locked cabinets in locked offices.

We may share some information with other researchers. They will be approved by our team. They will not be able to link study IDs to names.

We will never use your child's name in any report. The information you give will always be combined with information from all other participants in reports.

Does my child have to be in this part of the study?

The decision to be in this part of the study is up to you. Your child's participation is voluntary. If you decide to participate and change your mind, your child can drop out of the study at any time. We will still use the information your child gave us unless you tell us not to use that information.

Your child's school and healthcare services will not be affected if you decide not to be in the study. We will not discuss your decision to participate or not to participate with anyone outside the study.

Who can I call if I have questions?

If you have questions about the study, you can call *<site PI or project coordinator>* at *<phone number>*. If you feel you have been harmed by participating in this part of the study, please contact *<site PI or*

project coordinator at *<phone number>*. If you have questions about your rights as a research participant, you can call the *<site IRB office contact>* at *<phone number>*.

We will give you a copy of this consent form to keep.

Informed Consent Statement for Parents of Children Younger than 18 Years

I have been told about the study. I know what is expected of my child. I was allowed to ask questions. I had all my questions answered. I give permission to enroll my child in this part of the study.

Signature of parent

Date/Time

Printed name (parent)

Printed name (child)

Signature of witness

Date/Time

Printed name (witness)

Informed Consent Statement for Legal Guardians of Young Adults 18 Years and Older

I have been told about the study. I know what is expected of my child. I was allowed to ask questions. I had all my questions answered. I give permission to enroll my child in this part of the study.

Signature of parent

Date/Time

Printed name (parent)

Printed name (child)

Signature of witness

Date/Time

Printed name (witness)

Study to Explore Early Development (SEED) Follow-up Studies

Assent Form for Children

We are asking you to be in a study. This study is by the Centers for Disease Control and Prevention (CDC). CDC wants to make people healthy and safe. CDC is working with research partners across the country to do the study. This form tells you more about the study.

What is this study about?

This is a study about how people learn. We want to see how people learn early and later in life.

Why do you want me to be in the study?

You were in a study when you were 2-5 years of age. We looked at how you learn. We now want to look at how you learn again. We will use this information to help people. Some of the people we help have different ways of learning.

What will I have to do?

You will be asked some questions. You will be asked to do activities like puzzles. You will also be asked to look at pictures on an iPad. The test will take about one hour. You can take a break or stop at any time.

Will I be hurt?

You might feel nervous. We will make sure you are calm and happy. You might get tired. You can take breaks or stop at any time. You will not be hurt.

Why should I be in the study?

You will not get anything from being in the study. You can help us learn about different ways people think. We use this information to make sure people get the help they need.

Will you tell anyone about this study?

We will only tell your parent(s) about the study. Your parents might tell your doctor or your school. We will not use your name in the study.

Do I have to be in the study?

You do not have to be in the study if you do not want. You can drop out of the study at any time.

What if I have questions?

You can ask the person who gave you this paper any questions. You can also ask your parent(s). Your parents have agreed for you to be in the study.

Agreement

I have been told about the study. I know what to do. I was allowed to ask questions. I had all my questions answered. I agree to be in this study.

Signature of participant

Date/Time

Printed name (participant)

Signature of witness

Date/Time

Printed name (witness)

Study to Explore Early Development (SEED) Follow-up Studies

Informed Consent Form for Young Adults

You are invited to be in a research study. This study is funded by the Centers for Disease Control and Prevention (CDC). CDC is a federal agency that works to improve the health and safety of people. CDC is working with research partners across the country to conduct the study. Your participation will help us learn how we can support different types of children and families as they grow older.

What is the purpose of the study?

This is a study on changes that happen between the preschool years and adolescence and young adulthood. Some of the changes we are interested in are health, healthcare, safety, services, and treatments. Another is how learning abilities change over time. We are inviting you now to this part of the study to look at changes in learning abilities.

One of our goals is to better support people with autism and other developmental delays or disabilities as they grow older. To reach our goals, we need different types of people and families to participate in the study.

Why am I being asked to be in this part of the study?

You are being invited to take part in this study because you participated in SEED in the past. Specifically, you completed an evaluation of early learning abilities between 2 and 5 years of age. Recently, your parent also completed a survey about your current health and development.

What will I have to do to be in this part of the study?

You will be asked to complete an evaluation of learning abilities. This involves answering questions and completing activities like puzzles. It also involves comparing pictures presented on an iPad. The evaluation will take about one hour. You can stop the evaluation at any time without penalty.

Why should I be in this part of the study?

There is no personal benefit for being in this part of the study. Your participation will help us learn more about how learning abilities change over time. This information may be used to help people with autism and other developmental delays and disabilities. One way to help people with autism and other developmental delays and disabilities is to offer better services and treatments.

Are there any risks involved with this part of the study?

There is little risk involved with the evaluation. You may feel nervous working with a new person. The person who gives the evaluation will make sure you are comfortable before testing begins. You may become tired during the evaluation. Short breaks will be given as needed. You will receive written results from the evaluation. You may get feedback that is unexpected and/or shows below average skills. We will tell you how to contact someone if you have questions. You are also encouraged to share results with your healthcare provider.

Is this going to cost me anything?

There are no costs for being in this part of the study.

Will I get anything after the evaluation?

You will receive a \$45 gift card for being in this part of the study. The gift card is to thank you for your participation. It can also be used to cover travel expenses.

You will receive written results within one month of the evaluation. The letter will explain each test you completed. It will explain your scores on each test. It will tell you how you performed compared to other people the same age. We encourage you to share these results with your healthcare provider.

We will send you a study newsletter up to two times per year. It will be emailed to you, or you can find it on our website at [SEED Newsletter | CDC](#). It will tell you what we are learning from the study.

Will my information I give be kept confidential?

Any information that identifies you will be kept confidential unless otherwise required by law. A study ID will be assigned to evaluation results. Only people working on the study will be able to link study IDs to names. The link will be kept on a password-protected computer. Evaluation forms will be kept in locked cabinets in locked offices.

We may share some information with other researchers. They will be approved by our team. They will not be able to link study IDs to names.

We will never use your name in any report. The information you give will always be combined with information from all other participants.

Do I have to be in this part of the study?

The decision to be in this part of the study is up to you. Your participation is voluntary. If you change your mind, you can drop out of the study at any time.

Any services you receive will not be affected if you decide not to be in the study. We will not discuss your decision to participate or not to participate with anyone outside the study.

Who can I call if I have questions?

If you have questions about the study, you can call *<site PI or project coordinator>* at *<phone number>*. If you feel you have been harmed by participating in this part of the study, please contact *<site PI or project coordinator>* at *<phone number>*. If you have questions about your rights as a research participant, you can call the *<site IRB office contact>* at *<phone number>*.

We will give you a copy of this consent form to keep.

Informed Consent Statement

I have been told about the study. I know what is expected. I was allowed to ask questions. I had all my questions answered. I agree to be in this part of the study.

Signature of participant

Date/Time

Printed name (participant)

Signature of witness

Date/Time

Printed name (witness)

Name _____ Sex: F M
 Last First MI
 ID # _____ Examiner _____
 School/Agency _____ Grade _____

	Year	Month	Day
Testing Date			
Birth Date			
Age			

Stanford
BINET
 Intelligence Scales
 Fifth Edition
 Record Form

Nonverbal (NV) Domain

	FR	KN	QR	VS	WM
Raw Scores: Level 1	ROUTING			4	4
Level 2	ROUTING	6	6	6	6
Level 3	ROUTING	6	6	6	6
Level 4	ROUTING	6	6	6	6
Level 5	ROUTING	6	6	6	6
Level 6	ROUTING	6	6	6	6
Raw Score Total					
NV Scaled Score Appendix A	+	+	+	+	=

Verbal (V) Domain

	FR	KN	QR	VS	WM
Raw Scores: Level 2	6	ROUTING	6	6	6
Level 3	6	ROUTING	6	6	6
Level 4	6	ROUTING	6	6	6
Level 5	6	ROUTING	6	6	6
Level 6	6	ROUTING	6	6	6
Raw Score Total					
V Scaled Score Appendix A	+	+	+	+	=

	FR	KN	QR	VS	WM
Sum of NV and V Scaled Scores					

Subtest Profile-Scaled Scores

	Nonverbal (NV)					Verbal (V)						
	FR	KN	QR	VS	WM	FR	KN	QR	VS	WM		
19	•	•	•	•	•	•	•	•	•	•	•	19
18	•	•	•	•	•	•	•	•	•	•	•	18
17	•	•	•	•	•	•	•	•	•	•	•	17
16	•	•	•	•	•	•	•	•	•	•	•	16
15	•	•	•	•	•	•	•	•	•	•	•	15
14	•	•	•	•	•	•	•	•	•	•	•	14
13	•	•	•	•	•	•	•	•	•	•	•	13
12	•	•	•	•	•	•	•	•	•	•	•	12
11	•	•	•	•	•	•	•	•	•	•	•	11
10	•	•	•	•	•	•	•	•	•	•	•	10
9	•	•	•	•	•	•	•	•	•	•	•	9
8	•	•	•	•	•	•	•	•	•	•	•	8
7	•	•	•	•	•	•	•	•	•	•	•	7
6	•	•	•	•	•	•	•	•	•	•	•	6
5	•	•	•	•	•	•	•	•	•	•	•	5
4	•	•	•	•	•	•	•	•	•	•	•	4
3	•	•	•	•	•	•	•	•	•	•	•	3
2	•	•	•	•	•	•	•	•	•	•	•	2
1	•	•	•	•	•	•	•	•	•	•	•	1

Appendix B

	Sum of Scaled Scores	Standard Score	Percentile Rank	% Confidence Interval
NVIQ				to
VIQ				to
FSIQ				to
FR				to
KN				to
QR				to
VS				to
WM				to

Composite Profile-Standard Scores

	NVIQ	VIQ	FSIQ	FR	KN	QR	VS	WM	
160									160
145									145
130									130
115									115
100									100
85									85
70									70
55									55
40									40

Trademarks to the Stanford Binet Intelligence Scales are used under an agreement with Houghton Mifflin Harcourt Publishing Company and the Riverside Publishing Company.

Additional copies of this form (#13297) may be purchased from PRO-ED, 8700 Shoal Creek Blvd., Austin, TX 78757-6897 800/897-3202, Fax 800/397-7633, www.proedinc.com

Fig. 1. Examples of types of discrimination on the NIH Toolbox Pattern Comparison Processing Speed Test.



Task Description: The NIHTB Pattern Comparison Processing Speed Test requires participants to identify whether two visual patterns are the “same” or “not the same” (responses were made by pressing a “yes” or “no” button). Patterns were either identical or varied on one of three dimensions: color (all ages), adding/taking something away (all ages), or one versus many (only ages 8–15 years; see Figure 1). Scores reflected the number of correct items (of a possible 130) completed in 90 s; as described above, items were designed to minimize the number of errors that were made (i.e., items with less than 75% accuracy during development were not included in the final version of this task). This test takes approximately 3 min to administer.

Reference:

Carlozzi, N. E., Tulsy, D. S., Chiaravalloti, N. D., Beaumont, J. L., Weintraub, S., Conway, K., & Gershon, R. C. (2014). NIH toolbox cognitive battery (NIHTB-CB): the NIHTB pattern comparison processing speed test. *Journal of the International Neuropsychological Society*, 20(6), 630-641.