

Dear Guardian,

Our research team is working to improve the Communication Complexity Scale (CCS), a scale that we created to help better assess the communication abilities of individuals with intellectual and developmental disabilities. We are currently recruiting participants and hope you might consider allowing your family member to participate in this important study. Your family's participation would help further this assessment so that it can eventually be shared with other clinicians and scientists and will also provide caregivers with information about your family member's communication abilities.

Participation would include a one-time visit with your family member at an agreed upon appropriate location. The participant would be administered a small battery of tests to assess his or her language, vocabulary, and communication skills. The participant's primary caregiver would also complete a collection of questionnaires. Compensation of \$50 will be provided for the participant's time.

We have included a few necessary forms for you to complete if you are willing to allow your family member to participate in our study. The forms are listed below including brief descriptions of their purposes. Please sign these forms and return them to our office in the self-addressed, stamped envelope that is provided.

- **Informed Consent Statement** – This form describes our study in further detail and outlines the details of your and your family member's participation. We have provided two copies of this form. We ask that you sign one to return to our office and keep one for your records.
- **Permission to Use Video Tape** – This form gives our project staff permission to video tape interactions with your family member and allows you to decide how these videos may be used.

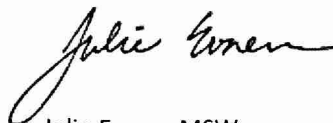
We hope you will consider participating in this important research study. Please feel free to contact us with any questions or concerns.

For more information related to this project, please visit: <https://lsidata.ku.edu/ccs/>

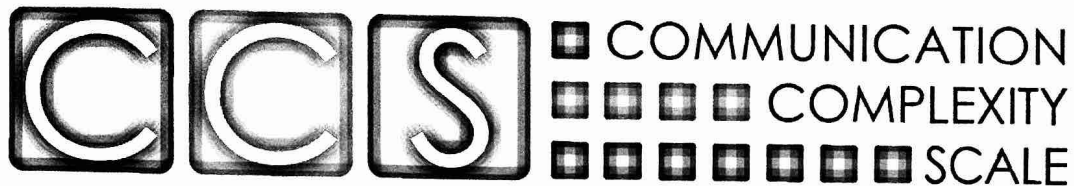
Sincerely,



Nancy Brady, Ph.D.
Principal Investigator
The Communication Complexity Scale
Email: nbrady@ku.edu
Phone: (785) 864-0762



Julie Evnen, MSW
Project Coordinator
The Communication Complexity Scale
Email: jevnen@ku.edu
Phone: (785) 864-1573



An Assessment that Focuses on Abilities
Project Recruitment

Research for a new communication assessment for people who speak or sign very few words
funded through the National Institute of Health
Results will improve assessment practices for children and adults.



Seeking Participants with the Following Characteristics:

- Between 3-60 years old
- Having an intellectual/developmental disability or delay including autism
- Functionally speaking or signing 0-20 words
- Able to complete activities & games by using hands and arms
- Using English as their first language

Participation: Complete a short activities based assessment in the participant's home, school, or other agency. Caregivers will also complete a few questionnaires with our staff. Total time commitment is approximately 1.5 hours, 30 minutes with the participant, and one hour with the parent or caregiver. Compensation of \$50 will be provided for the participant's time and a report will be written about the results.

Contact Julie Evnen at 785-864-1573 or jevnen@ku.edu to learn more.

OR

Visit our website: <https://lsidata.ku.edu/ccs/>

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1052 Dole, 1000 Sunnyside Avenue
Lawrence, KS 66044

INFORMED CONSENT STATEMENT: FOR PARENTS

The CCS: A Treatment Outcome Measure

INTRODUCTION

We are researchers with the Life Span Institute at the University of Kansas. We support protection for human subjects participating in research. Please read the following information about a study we are conducting with individuals who are **between 3-60** years of age and who are either not yet talking or who are only saying a few words. At the end of this letter is a place for you to sign if you agree to participate. If you do not want to participate, do not sign the form. If you sign the form you can change your mind later and stop participating.

PURPOSE OF THE STUDY

We are aiming to further develop and validate the Communication Complexity Scale (CCS), a measure of communication, for use in future clinical trials research. The CCS can be used with children and adults with severe disabilities such as autism, Rhett syndrome, and Fragile X syndrome (FXS). The focus is on developmentally early communication, beginning with alertness to changes in the environment and progressing through beginning word use. We will compare communication measured with the CCS to other measures of communication and general development.

PROCEDURES

We will assess participant's communication with an interactive assessment we have developed (Scripted Interaction Protocols). This assessment includes 12 activities such as blowing bubbles and reading a book and takes about 30 minutes. This activity will be videotaped so we can watch it later to evaluate your child's communication using the scale we are developing called the Communication Complexity Scale, or CCS. Videotapes will be digitized and members of our research team will watch the videos to score communication interaction of your child using the CCS.

We will administer 4 different tests. **The Peabody Picture Vocabulary Test-4 is a test of vocabulary understanding. We will give this test on the same day that we give the Scripted Interaction Protocol. The other three assessments rely on information from the parent or caregiver. We will set up an interview or interviews with you to collect information for these three assessments: the Social Communication Questionnaire--a questionnaire about social communication, the Vineland II-- a measure of adaptive behavior in communication, daily living skills, socialization, and motor skills, and the Communication Matrix-- an assessment of early communication. All together, these tests should take about one hour of your time. We can complete these assessments on the same or different days at your convenience. We would like to complete all the assessments within 1 week of completing the Scripted Interaction Protocol.**



RISKS

We do not know of any risks associated with this study.

BENEFITS

Participants in this study will be helping us learn more how to describe the early stages of communication development including vocalizations, gestures, and eye gaze. In addition we will share our test results with parents and teachers if requested.

PAYMENT TO PARTICIPANTS

We will pay you \$50.00 for your participation. We are offering this payment because we know that your time is valuable and we appreciate your time. Research assistants will ask you to fill out forms that include your social security number to comply with federal and state accounting regulations.

CONFIDENTIALITY

We will not use your name or your child's name, **or any identifying information when presenting the results of our research.** We will ask you about personal information such as the diagnosis of your child but this information will not be linked to your or your child's name. A code number will be assigned to each participant and a password protected copy of participants' identity will be kept on a secured server in files that only Drs Brady and Fleming will be able to access.

The videotapes and data records we collect will be kept up to 10 years following the completion of the study, in locked cabinets in locked offices that are only accessible by Drs Brady and Fleming and the project coordinator. After 10 years, all videos and associated data will be shredded and destroyed using University shredding services. Electronic records related to the study will also be stored according to participant's code number and will be kept in a secure database and server. Access will be limited by firewall, IP address of computer workstations and individual university logins of only approved researchers and staff

The researchers will not share information about you unless required by law or unless you give written permission. We are required to give your social security number to federal agencies because we are paying you. Our copy of the consent form and all the information you give to us will be kept along with participants test results, videos and observation records in locked file cabinets in Dr. Brady's research lab at KU for up to 10 years after the end of the study. After this time, we will destroy all files.

By signing this form you give permission for us to share the de-identified information about your child's communication at any time in the future.

REFUSAL TO SIGN CONSENT AND AUTHORIZATION

You are not required to sign this Consent and Authorization form. You may refuse to sign it. If you refuse to sign this form you still have the right to participate in other programs at the University of Kansas. However, if you refuse to sign, you cannot participate in this study.



CANCELLING THIS CONSENT AND AUTHORIZATION

You may change your mind about participating in this study. You may also decide that you don't want us to share information about you or your child. To cancel your permission, write a letter saying that you do not want us to share your information. Send this letter to Nancy Brady. Her address is at the bottom of this letter. If you cancel permission, the researchers will stop collecting information about your child. The research team may still share the information they gathered before you cancelled your permission, however.

QUESTIONS ABOUT PARTICIPATION

Please ask Dr. Nancy Brady or Dr. Kandace Fleming any questions about the study or about your participation in the study. Their addresses and phone numbers are at the bottom of this letter.

PARTICIPANT CERTIFICATION:

I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the study: **I understand that if I have any additional questions about my rights as a research participant, I may call (785) 864-7429, write the Human Subjects Committee Lawrence Campus (HSCL), University of Kansas, 2385 Irving Hill Road, Lawrence, Kansas 66045-7568, or email irb@ku.edu.**

I agree to take part in this study as a research participant. I also agree that my child/ward may participate. I am over 18 years of age and I have received a copy of this Consent and Authorization form.

_____ Participant's Name	_____ Participants Date of Birth
_____ Print Parent/Guardian's Name	_____ Date
_____ Parent/Guardian's Signature	_____ Email

Address: _____

Phone Number: _____

Researcher Contact Information:

Nancy Brady, PhD
Principal Investigator
Life Span Institute
3008 Dole, 1000 Sunnyside Ave.
University of Kansas
Lawrence, KS 66045
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_____ Print Parent/Guardian's Name	_____ Date
_____ Parent/Guardian's Signature	_____ Email

Address: _____

Phone Number: _____

Researcher Contact Information:

Nancy Brady, PhD Principal Investigator Life Span Institute 3008 Dole, 1000 Sunnyside Ave. University of Kansas Lawrence, KS 66045 785-864-0762 nbrady@ku.edu	Kandace Fleming, PhD Co-Principal Investigator Life Span Institute 1052 Dole, 1000 Sunnyside Ave. University of Kansas Lawrence, KS 66045 785-864-0742 kfleming@ku.edu	Julie Evnen, MSW Project Coordinator Life Span Institute 1000 Sunnyside Ave. University of Kansas Lawrence, KS 66045 785-864-1573 jevnen@ku.edu
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OPTIONAL: PERMISSION TO USE VIDEOTAPE FOR ADDITIONAL PURPOSES

By checking the boxes below I _____ hereby give my consent to allow project staff of the CCS measurement project to use videotaped data of my child for the purpose of training, education, and feedback. **Sharing videotapes is optional and will not affect your participation in this research study.** I understand I can revoke my permission at any time and it will not affect my participation in the study.

☐ I give permission to use videotapes of my child to be shared with select researchers and students. **Checking this box indicates that videos may be shown at conferences or in meetings with other researchers.**

☐ I give permission to use videotapes of my child on researchers' websites for educational and community training purposes. **Checking this box indicates that videos may be available to anyone with an internet connection.**

Name: _____

Signature: _____

Date: _____

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The University of Kansas

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Dole Human Development Center
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Lawrence, KS 66045

Julie Evnen

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