FLORIDA STATE
UNIVERSITY

FIRST WORDS® Project • College of Medicine

Providing Early Identification & Referral for Families of Infants & Toddlers with Communication Delays

BABY NAVIGATOR PORTAL RESEARCH STATEMENT

Principal Investigator: Amy M. Wetherby, PhD, Florida State University

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What is the purpose of our research?

The purpose of our research is to help families of infants and toddlers to learn about early milestones and how to support your child's development. We want to determine if the Baby Navigator Portal tools and resources, including the Social Communication (SoCo) Growth Charts and SoCo CheckUp, provide helpful information for families, help decrease the age that communication delays or autism are detected, and improve the development of early social communication skills.

We will use SoCo Growth Chart data, SoCo CheckUp scores, usage data from tools and resources accessed via the Baby Navigator Portal, and information from the home observation videos and diagnostic evaluations to help us create a more efficient, cost-effective, mobile screening application for use with infants and toddler to find the early signs of communication delay and autism as young as possible. We also want to provide tools and resources to help parents act at the first signs of communication delay and autism to improve their child's communication/language and social engagement.

What will you be asked to do?

You and your child are being invited to be in our research because you have a young child and are interested in learning about social communication milestones and early development. You will be asked to use the tools and resources available through the Baby Navigator Portal as much or as little as you choose. You will be invited to explore and chart your child's development using the SoCo Growth Charts, to screen your child using the SoCo CheckUp, and to use the educational materials. This will take as much or as little time as you choose. There are no costs for you to participate in this research.

We will track your usage and collect data you provide in any of the tools and resources you choose to use, which may include: SoCo Growth Charts, SoCo CheckUp, E-monitoring questions sent to you, 16 by 16 Lookbooks, About Autism in Toddlers (AAT), ASD Video Glossary, How-To Guide for Families and the How-To Guide Online Guided Tour.

What are the risks of participating in this research?

There are very minimal risks associated with participating in this research. The activities are normally encountered in daily life. You can choose which activities you do. There is a slight risk of a loss of privacy, which we do our best to minimize.

What are the benefits of participating in this research?

You may not benefit directly from your participation in this research. The information you learn from the online tools and resources may help you support your child's development and figure out if your child has a communication delay. This research may benefit other people in the future through the development of better tools for identifying young children with developmental disorders and getting them intervention as soon as possible to improve their outcomes.

Can I leave the research?

Participation in this research is your choice and you can stop at any time. The decision to withdraw from the research will not affect any other benefits or services outside of this research. To leave this research project, please contact the FIRST WORDS Project at support@babynavigator.com or by phone at 850-488-5780.

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Confidentiality and Privacy of your data

Every effort will be made to keep your information confidential to the extent allowed by law, however, this cannot be guaranteed. The information from you and your child's participation in this research will be saved indefinitely on a secure, password-protected, HIPAA-compliant computer server. Whenever possible, a study ID number, rather than you or your child's name, will be used on research records.

Research staff may release information about you and your child when you say it is okay. For example, you may give permission to release information to healthcare providers, insurers, or others not connected with the research. You can share information about your involvement in this research. You can have access to you and your child's study information.

What will happen to your information after the research is over?

All of the research information about you and your child will be stored indefinitely on a secure, password-protected, HIPAA-compliant computer server. We will keep all of your research information indefinitely. In the future, our research team may continue to use your information for other research without notifying you.

We will share what we learn (the research results) with other researchers and the general public. And we may place data from this study into public databases. We will NOT share any audio or video files of you and your child. Before your data is shared, we will remove or code any personal information that could identify you or your child. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the data we share. Despite these measures, we cannot guarantee that your personal data will stay anonymous.

Contacts and Questions for the research team

At any time, you may contact research staff with any questions or complaints about the research.

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Contact information for questions about your rights as a research participant

If you have any questions or concerns about your rights as a research participant, or regarding this study and would like to talk to someone other than the researcher, you are encouraged to contact the FSU IRB at 850-644-7900 or by email at humansubjects@fsu.edu, or by writing or in person at 2010 Levy Street, Research Building B, Suite 276, FSU Human Subjects Committee, Tallahassee, FL 32306-2742.