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Official Title: Utilizing Smart Speaker Technology to Deliver Parenting Education Support to Parents of Young Children

Principal Investigators: Carol W. Metzler and David Smith, Ph.D.

Oregon Research Behavior Interventions Strategies, dba Influents Innovations

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**[NOTE: CONSENT WILL BE ADMINISTERED ON QUALTRICS]**

## **Informed Consent for Participation in Talk Parenting Study**

**Study Title:** Utilizing Smart Speaker Technology to Deliver Parenting Education Support to Parents of Young Children

**Principal Investigators:** Carol W. Metzler, Ph.D. and David R. Smith, Ph.D.

**Sponsor:** National Institute of Child Health and Human Development, grant # R43 HD101190-01A

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### **SUMMARY**

We are inviting you to take part in a research study. You do not have to be in the study if you do not want to be. You can also decide to be in the study now and change your mind later.

**This study is about** developing and testing a smart speaker (Alexa)-based program for parents of young children, to guide parents in helping their children develop a healthy bedtime routine and be cooperative around bedtime.

**If you take part in this study, we will ask you to** (1) fill out a questionnaire (about 30 minutes) that asks about your child's behavior and sleep habits, your parenting style, and your family relationships; then (2) be sent an Echo Dot smart speaker ("Alexa") and instructions on setting up the Talk Parenting program; (3) use the Talk Parenting Bedtime Routine program with your child at least two times per week for about four weeks; then (4) fill out another questionnaire (same questions again, plus your opinion of the program). The Talk Parenting Bedtime Routine is an Alexa-based tool that guides you in setting up a fun bedtime routine for your child and then guides you and your child through the routine at bedtime.

**The most serious risks related to being in this study are** loss of privacy if information about you is not kept confidential. The information we will collect from you is what you tell us on the questionnaires and what is recorded by Alexa when you and your child are using the Talk Parenting Bedtime Routine program.

**The main benefits of being in this study are** that you and your child may enjoy interacting with Alexa and the Talk Parenting program. In addition, you will be able to keep the Echo Dot (Alexa) device and auxiliary battery pack you use for the study.

**We plan to make the results of this study public but we will not include your name or other identifying information.**

**We would like you to ask us questions** if there is anything about the study that you do not understand. You can call **Alexia at 786-559-6583** or email us at **[bedtime@influentsin.com](mailto:bedtime@influentsin.com)**.

You can also contact the ORI Office for the Protection of Human Subjects with any concerns that you have about your rights or welfare as a study participant. This office can be reached at (541) 484-2123 or by email at [kathryn@ori.org](mailto:kathryn@ori.org).

There are more details about the study in the following pages.

## **Informed Consent for Participation in the Talk Parenting Study**

**Study Title:** Utilizing Smart Speaker Technology to Deliver Parenting Education Support to Parents of Young Children

**Principal Investigators:** Carol W. Metzler, Ph.D. and David R. Smith, Ph.D.

**Sponsor:** National Institute of Child Health and Human Development, grant # R43 HD101190-01A

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### **STUDY DETAILS**

#### **1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?**

You are invited to participate in a research study to develop and test a smart speaker (Alexa)-based program for parents of young children, which is designed to guide parents in helping their children develop a healthy bedtime routine and be cooperative around bedtime. This study is being conducted by Carol W. Metzler, Ph.D. of Oregon Research Institute and David R. Smith, Ph.D. of Influents Innovations, in **Springfield**, Oregon and is funded by the National Institute of Child Health and Human Development, grant # R43 HD101190-01A. We want everyone in the study to understand what it is about. Please read this form and ask any questions you may have before agreeing to participate in the study.

#### **2. WHAT WILL YOU BE ASKED TO DO IN THIS RESEARCH STUDY?**

If you decide to participate, you will be asked to complete two questionnaires and use the Talk Parenting Bedtime Routine program at least two times per week for four weeks.

First, we will ask you to fill out an online questionnaire two times (now, and again in about four weeks) that will take about 30 minutes to complete. The questionnaire will ask about your child's behavior and sleep habits, your parenting style, and your family relationships. The second questionnaire 4-5 weeks later will ask you these same questions again and also ask you your opinions about the Talk Parenting Bedtime Routine program. You will receive \$20 for completing each questionnaire (for a total of \$40).

After you complete the first questionnaire, we will ask you to use the Talk Parenting Bedtime Routine program with your child at least two times per week for four weeks.

We will send you an Echo Dot smart speaker ("Alexa") and instructions on setting up the Talk Parenting program within Alexa. The Talk Parenting Bedtime Routine is an Alexa-based tool that guides you in setting up a fun bedtime routine for your child and then guides you and your child through your routine at bedtime. You will decide what bedtime activities should happen and in what order, and then the Bedtime Routine will involve songs, stories, and activities to gently motivate your child and help him/her develop bedtime cooperation, calming skills, and positive habits. You and your child will tell Alexa when you have finished each activity of the bedtime routine and are ready to move on to the next activity. A "Help" feature will be available to you to assist with challenges or problems. You will receive access to the Talk Parenting Bedtime Routine program for free, and you will get to keep the Echo Dot and auxiliary battery pack after the study is over. As part of your participation in the study, we ask that you commit to using the Talk Parenting Bedtime Routine at home with your child at least twice per week during the four-week period. We will send you a couple of reminders each week to use the program during this time.

Amazon's Alexa database will audio-record what is said to Alexa when you and your child are using the Talk Parenting Bedtime Routine program. These recordings will be saved as transcripts, and will be analyzed by the research team to understand how people are using the program, how the program is responding to what parents and children are saying, and any technical difficulties with the program. The use of these audio-recordings and

transcripts will be limited to this research project and to training of project staff under the supervision of the project directors. Project staff may at any time copy, erase, or destroy these recordings. You may review the recordings, and request that any or all of the information about you be destroyed.

By participating in the study, you are making an important contribution to research on how to best help families build healthy bedtime routines. Please make sure that you understand what you are agreeing to and that you can make the commitment to do all of the study activities over the next 4-5 weeks. You will still have the choice to stop your participation if you have concerns, but it's important to the study that parents be committed to doing as much of the study activities as possible.

### **3. WHAT ARE THE RISKS AND WHAT WILL BE DONE TO REDUCE THE RISKS?**

There are some possible risks involved for participants. We want the people who are in the study to know what those risks are, and what we do to make those risks as small as possible. They are:

- We will be getting personal information about your child and family from you – on the questionnaires you fill out and in the audio-recordings of your and your child's interactions with the Talk Parenting program. There is always the possibility that someone who is not authorized might see this information. We take the following precautions to prevent any unauthorized person from having any access to the information you give us:
  - a. Any information you give us will be kept strictly confidential. All information will be kept in locked electronic files. We will remove all names from all the information we get (except this consent form). ID numbers will be assigned to the information you give us, and only authorized staff will have access to the locked electronic file that links your name to your ID#.
  - b. All transcripts and audio-recordings of your and your child's interactions with Alexa that are stored on Amazon's back-end database are kept private and fully password protected, and will be accessible only to key project staff. Your family's account will be created specifically for the study purposes only, and only the Talk Parenting program will be enabled on the account, which will prevent serious privacy violations from occurring. Any statements from visitors to your household recorded by Alexa while Talk Parenting is active will be removed from the transcript and not analyzed. At the end of the study, we will de-register the device from your study account and deactivate the account. You will then be free to connect the Echo device to your own Amazon account.
  - c. We have a "Certificate of Confidentiality" which is a legal assurance from the federal government, which will help us protect your privacy. In rare cases, identifiable records could be subpoenaed. If this happens, ORI's lawyer will work with the courts to protect your privacy.
  - d. We will not give information to anyone unless you provide a signed release telling us to do so, or unless we have reason to suspect: (1) abuse, neglect, or endangerment of a child or elder; (2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these situations, we may have to make a report to the appropriate authorities.
  - e. A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At the very end of the project, we will post a study consent form and a summary of the research results to the website. The consent form and results will not have names on them. You can search this website at any time.

- f. The information that you give us will only be used for this study. We will not share information about you with others or use it in future studies without your consent. There is still a chance that someone could figure out that the information is about you.
- You may feel uncomfortable with some of the questions we ask you on the questionnaire. You are free to not answer any question that you do not want to answer. Please let us know if you find the questionnaire stressful or distressing.
- It is possible that you or your child may find interacting with the Talk Parenting program stressful or frustrating, or that it might not work for your family, or worsen your bedtime experience. The program has been carefully designed, however, to be helpful and supportive. If you have a significant negative experience, we would want to know about that and work with you to resolve it. And of course, you are also free to stop participating at any time.
- It is also possible that you may be experiencing serious life difficulties that are beyond the ability of a technology-based program to help you with. A technology-based program is not a substitute for professional help for serious difficulties you might be having. If you feel you are having an emergency situation, please seek outside professional help. If you are experiencing serious difficulties, please let us know (Alexia at 786-559-6583), and we will work with you to find resources that can help you.

#### **4. WHAT ARE THE BENEFITS OF THIS STUDY?**

There are also some benefits to you for taking part in this research project. You will be able to keep your Amazon Echo Dot (Alexa) device and auxiliary battery pack used in the study. In addition, you and your child may enjoy interacting with the Alexa device and the Talk Parenting program. Bedtime struggles are a common issue in many families of young children, and you may enjoy being able to contribute to the development of a new program to help families with bedtime problems. Finally, this study could contribute to our knowledge about how we can use technology-based programs to promote positive parenting techniques and family and child well-being.

#### **5. WHAT HAPPENS IF YOU ARE INJURED OR HARMED?**

It is important that you promptly tell the researchers if you believe that you have been injured or harmed because of taking part in this study. You can tell the researcher in person or call him/her at the number listed below. If you have been injured or harmed because you are in this study, project staff will work with you to resolve any difficulties caused by your study participation. Influents Innovations and Oregon Research Institute are unable to pay for the treatment of research-related injuries.

#### **6. DO YOU HAVE A RIGHT TO WITHDRAW FROM THE PROJECT?**

Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty or loss of benefits you might otherwise receive. If you decide to participate, you can stop participating any time without penalty. If you decide to withdraw from the project, you can still keep the money you have received for completing the questionnaire.

If you have questions about the research at any time, or if you have a visual or other impairment and require this material in another format, please call Alexia at 786-559-6583. If you have questions about your rights as a research subject and/or research-related injury, call the Office for the Protection of Human Subjects, Oregon Research Institute, (541) 484-2123. ORI's TDD number is 800-735-2900. You will be given a copy of this form to keep.

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## 7. WHAT DOES MY AGREEING TO PARTICIPATE ON THIS CONSENT FORM MEAN?

Your clicking “I agree to participate in the Talk Parenting study” below indicates (1) that you have read and understand the information provided above, (2) that you willingly agree to participate, (3) that you willingly agree to allow your child to participate, (4) that you understand that you may withdraw your consent at any time and stop your and your child’s participation at any time without penalty, and (5) that you have received a copy of this consent form.

- I agree to participate in the Talk Parenting study.

Participant name: \_\_\_\_\_

Your child’s name: \_\_\_\_\_

Date: \_\_\_\_\_

### **FOR SPOUSES, PARTNERS, AND OTHER ADULTS IN THE HOUSEHOLD:**

Your spouse/partner has agreed to participate with your child in the Talk Parenting study, as described above. You are not being asked to provide any questionnaire data and you are not necessarily expected to use the Talk Parenting Bedtime Routine, but you are free to interact with the Talk Parenting program if you choose to. Because you may interact with the Talk Parenting program on Alexa as a member of your household, it is important for you to know that Amazon’s Alexa database will audio-record what is said to Alexa (or said near Alexa) while the Talk Parenting Bedtime Routine program is being used. These audio recordings will be saved as transcripts, and will be analyzed by the research team to understand how people are using the Talk Parenting program, how the program is responding to what parents and children are saying, and any technical difficulties with the program. In order for your spouse/partner and child to participate in the Talk Parenting study, we need your consent to these recordings as well.

The use of these audio-recordings and transcripts will be limited to this research project and to training of project staff under the supervision of the project directors. Project staff may at any time copy, erase, or destroy these recordings. You may review the recordings, and request that any or all of the recordings of your voice be destroyed. All transcripts and audio-recordings of your family’s interactions with Alexa that are stored on Amazon’s back-end database are kept private and fully password protected, and will be accessible only to key project staff. Your family’s account will be created specifically for the study purposes only, and only the Talk Parenting program will be enabled on the account, which will prevent serious privacy violations from occurring. Any statements from visitors to your household recorded by Alexa while Talk Parenting is active will be removed from the transcript and not analyzed. At the end of the study, we will de-register the device from your study account and de-activate the account. You will then be free to connect the Echo device to your own Amazon account.

Your clicking “I consent to audio-recordings of what I say to Alexa or near Alexa as part of my family’s participation in the Talk Parenting study” below indicates (1) that you have read the above information and understand that what you say to Alexa or near Alexa when the program is active will be audio-recorded and may be reviewed by the study team, (2) that you willingly consent to these recordings as part of your family’s

participation in the Talk Parenting study, and (3) that you understand that you may withdraw your consent at any time.

- I consent to audio-recordings of what I say to Alexa or near Alexa as part of my family's participation in the Talk Parenting study.

Your Name: \_\_\_\_\_

Date: \_\_\_\_\_