

ORI IRB# 00000278

Protocol Version April 14, 2021

Official Title: Integrated Smart Speaker/Mobile Application to Promote Positive  
Parenting Among Caregivers of Youth with Challenging Behaviors

Principal Investigators: Oregon Research Behavioral Interventions Strategies, Inc. dba  
Influents Innovations

Award No. 1R43MH124577-01A1

Protocol Version Date April 14, 2021

Documents: Consent and Assent Forms

## **Informed Consent for Participation in the FamilyNet Study**

**Study Title:** FamilyNet

**Principal Investigators:** David R. Smith PhD, Edward G. Feil, PhD, and Carol W. Metzler, PhD

**Sponsor:** National Institutes of Health 1 R43 MH124577-01A1

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### **STUDY DETAILS**

We are inviting you and your 10-17 year old child to participate in a research study which will test a combined smart speaker/mobile application to help families create solutions to common family conflicts and promote positive parenting among caregivers of youth with challenging behaviors. You do not have to be in the study if you do not want to. You can also decide to be in the study now and change your mind later. This study is being conducted by David R. Smith, PhD, of Influent Innovations, and Edward G. Feil, PhD, and Carol W. Metzler, PhD, of Oregon Research Institute in Springfield, Oregon and is funded by the National Institutes of Health (grant #R43 MH124577-01A1). 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.

### **WHAT WILL I BE ASKED TO DO IN THIS RESEARCH STUDY?**

If you take part in this study, we will ask you and your 10-17 year-old child to use the FamilyNet smart speaker and mobile app program over a 4-week period and complete some surveys.

Before you start using the FamilyNet program we will ask you to complete an online questionnaire that will take about 30 minutes, and you will receive \$25.

Then, you will be asked to take part in a brief phone call (10-15 minutes). In this phone call, we will orient you to the FamilyNet program, assist you in downloading and installing the FamilyNet mobile app on your smartphone, help you select one positive behavior to work on for your child, and get you started with monitoring that behavior.

After you have monitored that behavior for 3 days, you will be sent an Amazon Echo Dot (Alexa), a Wi-Fi adaptor, and written instructions for the FamilyNet program.

Next, you and your 10-17 year-old child will be asked to take part in a 2-hour individual Zoom session with a project staff member. During the session, we will ask you and your child to identify achievable goals for your child's positive behavior, and possible rewards for achieving those goals. You and your child will also be shown how to use the FamilyNet technology (web app on your smartphone and Alexa smart speaker).

You will be asked to use the FamilyNet program for 4 weeks. On the FamilyNet mobile app and Alexa smart speaker, you and your child will record information (for example, the behavior completed, goals achieved, and rewards given) and receive messages and reminders about your progress toward your goals.

After 4 weeks, you will be asked to complete a second questionnaire online and receive \$50. The questionnaires will ask you about your parenting practices and your child's behavior, as well as how easy it was to use FamilyNet and your satisfaction with the FamilyNet system.

Your child will also be asked to complete online satisfaction questionnaires after the 4-week period of using FamilyNet, to find out how satisfied they are with FamilyNet as well. Your child will receive \$20 for completing this questionnaire.

At the end of the study, you will be asked to return the Wi-Fi adaptor to the project offices, but you will be free to keep the Echo Dot device.

Amazon's Alexa database will audio-record what is said to Alexa when you and your child are using the FamilyNet 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 youth 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 solve common problems. 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.

## **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:

1. 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 FamilyNet 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 number.
  - b. All written records 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.
  - c. Your family's Alexa account will be created specifically for the study purposes only, and only the FamilyNet program will be enabled on the account, which will prevent serious privacy violations from occurring. Please inform visitors to your household that Alexa may record their voice if they speak near or to Alexa while FamilyNet is activated.
  - d. At the end of the study, we will remove the device from your study account and close the account. You will then be free to connect the Echo Dot device to your own Amazon account.
  - e. 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.

- f. 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; or (2) that someone is in immediate danger of seriously hurting themselves or someone else. In these situations, we may have to make a report to the appropriate authorities.
  - g. A description of this study is 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.
  - h. 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 small chance that someone could figure out that the information is about you.
- 2. 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 upsetting.
  - 3. It is possible that you or your child may find interacting with the FamilyNet program stressful or frustrating, or that it might not work for your family. 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.
  - 4. 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 (at [familynet@influenzsin.com](mailto:familynet@influenzsin.com) and 786-559-6583), and we will work with you to find resources that can help you.

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

There are also benefits to this study:

- 1. You and your child may be helped by your use of the FamilyNet tool, by creating solutions to common family conflicts, increasing positive interactions, and reducing negative interactions.
- 2. You will be able to keep your Amazon Echo Dot device after the study. You will have access to all capabilities on Alexa that are pre-enabled by Amazon and come with the device (for example, playing music and podcasts; providing information [news, weather, traffic, statistics, facts]; setting timers and alarms), and you will be able to allow additional activities after the study is over and you move your access from our research Amazon account to your own Amazon account.
- 3. You may enjoy interacting with the Alexa device and providing feedback on your experience to aid the development of a new program to help families. The study could add to our knowledge about how technology-based interventions may be used to help families solve behavior challenges and promote positive parenting techniques and family and child well-being.

## **WHAT HAPPENS IF I AM 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 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. Influent Innovations and Oregon Research Institute are unable to pay for the treatment of research-related injuries.

## DO I 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 do decide to participate, you can stop participating any time without penalty.

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.

## WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?

Your signature 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 (4) that you have received a copy of this consent form.

For a copy of this consent, [CLICK HERE](#)

- ☐ I agree to participate in the FamilyNet study.
- ☐ I decline participation in the FamilyNet study.

Parent Participant Name:

Name of your 10-17 year-old child who will participate:

Parent Participant Signature:

×

SIGN HERE

clear

Date Signed:

	Month	Day	Year
Please select:	<input type="text"/>	<input type="text"/>	<input type="text"/>

Please confirm your contact information:

**Name:** \${e://Field/RecipientFirstName} \${e://Field/RecipientLastName}

**Email:** \${e://Field/RecipientEmail}

**Mobile number:** \${e://Field/Mobile}

- ☐ Yes, this information is correct  
☐ No, this information is not correct (please correct on the next page)

Please enter your correct contact information:

Your name:

Your email address:

Your mobile phone number:

Please enter your correct contact information:

Alternative email:

Alternative phone number:

Street address:

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

Your spouse/partner has agreed to participate with your child in the FamilyNet study, as described above. You are not necessarily expected to use the FamilyNet program, but you are free to interact with the FamilyNet program if you choose to. Because you may interact with the FamilyNet 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 FamilyNet is activated and 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 FamilyNet 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 FamilyNet study, we need your consent to these recordings as well.

The use of these audio-recordings and written records 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 FamilyNet program will be enabled on the account, which will prevent serious privacy violations from occurring. Please inform visitors to your household that Alexa may record their voice if they speak near or to Alexa while FamilyNet is activated. 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 Dot 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 FamilyNet 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 FamilyNet study, and (3) that you understand that you may withdraw your consent at any time.

For a copy of this consent, [CLICK HERE](#)

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

Your Name:

Date (mm/dd/yyyy):

Your Name:

Date (mm/dd/yyyy):

Your Name:

Date (mm/dd/yyyy):

Family Net is a research project funded by the National Institutes of Health, grant #1 R43 MH124577-01A1. Family Net is a partnership of Influenza Innovations and Oregon Research Institute and is directed by Dr. David Smith at Influenza Innovations and Dr. Edward Feil and Dr. Carol Metzler at Oregon Research Institute. The content of the project is solely the responsibility of the project directors and does not necessarily represent the official views of the National Institutes of Health.

## YOUTH AGREEMENT TO PARTICIPATE

### IN THE EVALUATION OF THE FAMILYNET PROGRAM

We are asking you to take part in our FamilyNet project, which is developing and testing a program to help families create solutions for common family conflicts. As part of this project, your family would use the FamilyNet program, which combines a smart speaker (Alexa) and mobile app, to focus on positive solutions. Your participation would start with a one-hour Zoom session with a project staff member and your parent, where we'll help you get set up with goals and rewards for achieving those goals. Then you and your parent would use the program for 4 weeks, to record behaviors completed, goals achieved, and rewards given, and receive messages and reminders about your progress toward your goals. We would also ask you to fill out a survey about your satisfaction with the program.

Alexa would record your interactions with the smart speaker device, and those recordings are saved to a very secure database that only authorized people on this project would be able to see. We would like for you to allow Alexa to record your interactions with your parent(s) on Alexa, and for us to access those recordings and save them so that we can analyze how the program is working. Also, we would like for you to fill out a questionnaire about your satisfaction with FamilyNet at the end of the project. You will receive \$20.

Your participation is voluntary, and you can refuse to participate or quit at any time.

For a copy of this consent [\*\*CLICK HERE\*\*](#)

Do you agree to allow Alexa to record your interactions with your parent(s) on Alexa, and to allow us to access the recordings and keep your recordings? And are you willing to fill out a satisfaction questionnaire at the end of the project?

- ☐ AGREE
- ☐ REFUSE

Date:

	Month	Day	Year
Please select:	<input type="text" value="v"/>	<input type="text" value="v"/>	<input type="text" value="v"/>

Youth's Name:

Witness for Youth's Assent:

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