

Informed Consent Form
Adapting a Parenting Intervention to Promote
Healthy Screen Time Habits in Young Children
with Behavior Problems
NCT05287685
March 24, 2022

FIU IRB Approval:	03/24/2022
FIU IRB Expiration:	10/28/2024
FIU IRB Number:	IRB-21-0463



ADULT CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Adapting a Parenting Intervention to Promote Healthy Screen Time Habits in Young Children with Externalizing Behavior Problems

SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** The purpose of the study is to collect information about a parent group that includes information about how to manage children's screen time.
- **Procedures:** If you choose to participate, you will be asked to join a parent group for FIU Summer Academy that will also include information about managing children's screen time. You will be asked to submit screenshots from the screen time management app of your child's most used mobile device 3 times. You will also be asked to complete questionnaires one month after the FIU Summer Academy program ends.
- **Duration:** This will take about 90 minutes for each of the 8 parent groups, plus 60 minutes to complete the questionnaire measures and screenshot submission.
- **Risks:** The main risk or discomfort from this research is that you may find sharing opinions and experiences in a group format to be uncomfortable.
- **Benefits:** The main benefit from this research is that you may learn strategies to better manage your child's screen time.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Participation:** Taking part in this research project is voluntary. Your decision to participate or not will in no way impact you or your child's involvement with FIU Summer Academy.

Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE STUDY

The purpose of this study is to collect information about the usefulness of a parent group that includes including strategies to manage children's screen time.

NUMBER OF STUDY PARTICIPANTS

If you decide to be in this study, you will be one 15 people in this research study.

DURATION OF THE STUDY

Your participation will involve attending the parent groups using the adapted curriculum instead of the parent groups using the original curriculum. Weekly groups will last for 90 minutes for the duration of the 8-week FIU Summer Academy program. You will be asked to take and submit screenshots from the screen time management app of your child's most use mobile device before, immediately after, and one month after the FIU Summer Academy program, which will take approximately 5 minutes each time

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(total 15 minutes). You also will be asked to spend approximately 45 minutes completing a set of online questionnaires about your parenting, stress, and child's media use.

PROCEDURES

If you agree to be in the study, we will ask you to do the following things:

1. Attend weekly parent groups using the adapted curriculum, instead of the parent groups using the original curriculum, for the duration of the 8-week FIU Summer Academy program. Parent groups will be videotaped for the purposes of studying how well the group leaders follow the curriculum.
2. Submit screenshots from the screen time management app of your child's most used mobile device, showing the total amount of time that the device was used and the three most used apps over one week. We will ask you to do this 3 times: before the program starts, at completion of the program, and one month after completion of the program.
3. Complete another set of online questionnaires about your experiences with your parenting, stress, and child's media use, one month after completion of the program.
4. Your child's classroom teacher during FIU Summer Academy will be asked to complete a questionnaire about your child's behavior at the end of the program.

RISKS AND/OR DISCOMFORTS

The study has the following possible risks to you: First, you may find sharing in a group format to be uncomfortable. Sharing is voluntary, and you are not required to share anything. Second, you may feel slightly uncomfortable being videotaped during the groups. The video recordings will be used only by the research team for the purposes of evaluating the work of the group leaders. Third, you may feel uncomfortable answering some questions in the online survey. You may skip any questions you do not feel comfortable answering. None of your responses will be shared with anyone outside of the research team, and all identifiable information will be removed from your responses.

BENEFITS

The study has the following possible benefits to you: You may learn strategies to manage your child's behavior and prepare your child for kindergarten. You also may learn strategies to manage your child's screen time and make your child's screen time more educational.

ALTERNATIVES

There are no known alternatives available to you other than not taking part in this study. You are free to choose not to participate in this additional study and this decision will in no way impact your involvement with FIU Summer Academy. Any new findings developed during the research which may relate to your willingness to continue participation will be provided to you.

CONFIDENTIALITY

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any report we might publish, we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the researcher team will have access to the records. However, your records may be viewed by authorized University or other agents who will also keep the information confidential.

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Video recordings will be transcribed and maintained on a secure computer and destroyed after 7 years. No names will be included in any of those transcriptions. Codes will be used to protect your identity and the identity of anyone else mentioned in the recordings.

If we learn about serious harm (or risk of harm) to you, your child, or someone else, we will take steps to protect the person endangered even if it requires telling the authorities without your permission. If we have reason to believe that your child is being abused, we will share our concerns with you and report this to the Florida Abuse hotline. In these instances, we would only disclose information to the extent necessary to prevent harm.

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can't be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative, or other proceedings.

There are circumstances where the Certificate doesn't protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies
- when information must be disclosed to meet FDA requirements (only required for FDA-regulated studies)
- if you give someone written permission to receive research information or you voluntarily disclose your study information
- if the researcher reports that you threatened to harm yourself or others
- in cases of child abuse or vulnerable adult abuse reported by the researcher
- if the investigator reports cases of contagious disease to the state

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this website at anytime.

USE OF YOUR INFORMATION

Identifiers about you might be removed from the identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

COMPENSATION & COSTS

You will receive a payment of \$10 for submitting the screenshots of your child's device use at each time point (up to \$30). You will receive a payment of up to \$55 for your completion of the online questionnaires one month after completion of the FIU Summer Academy program. There are no costs to you for participating in this study.

RIGHT TO DECLINE OR WITHDRAW

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to participate or if you quit the study early, and your participation in FIU Summer Academy will not be affected. The

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investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Dr. Shayl Griffith at Florida International University, 11200 SW 8th St Miami, FL 33139, 305-448-9976, shagriff@fiu.edu.

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

As part of the FIU Summer Academy program evaluation study you completed questionnaires and your child completed cognitive and academic assessments. Do you agree to share your and your child's data from the FIU Summer Academy program evaluation study for use in this additional study?

(initial here)

YES _____ NO _____