

Official Title: Optimizing an Evidence-Based, Disseminable, Free Internet-Based Parenting Program

NCT Number: NCT05689736

Date of document: 3-20-2023

2006. Online Consent Form

NOTE TO REVIEWER:

PROJECT INFORMATION AND STUDY LOGOS DISPLAYED ON TOP BANNER OF EACH WEBSITE PAGE/SCREEN.

IF ELIGIBLE, PARENT WILL MOVE SEEMLESSLY FROM THE SCREENER TO CONSENT PPT TO THE ONLINE CONSENT FORM

ON THE CONSENT PAGE, PARENTS CAN:

- READ FULL CONSENT FORM ON SCREEN 1,
- VIEW THE PPT (OPTIONAL), AND
- COMPLETE THE ONLINE CONSENT FORM.

PARENTS ARE REQUIRED TO CHECK BOXES 1 THROUGH 4 ON SCREEN 2, TYPE THEIR NAME AND PROVIDE CONTACT INFORMATION.

PARENTS WILL HAVE THE ABILITY TO DOWNLOAD/PRINT AN AUTO-GENERATED CONSENT FORM FOR THEIR RECORDS.

ONLINE CONSENT FORM, SCREEN 1:

Thank you for your interest in the Essentials for Parenting Toddlers and Preschoolers (EFP) study! If you would like to view a brief PowerPoint that describes the study and what participating means, click on the following link:

<<PROGRAMMER: PLEASE INSERT LINK TO PPT. PPT OPENS IN SEPARATE WINDOW. WHEN PARENT CLOSSES IT, COMES BACK TO ONLINE CONSENT FORM, SCREEN 1>>

Purpose of the Study

The study is being led by New York University and Westat, a research firm, on behalf of the National Institutes of Health, also known as the NIH. We are looking for 800 parents of toddlers to help us learn how to best engage parents in the EFP online parenting program.

As a parent of an 18-to 36-month old, your input will help us make the website better. We will give you access to one of several special new versions of the EFP program that we believe will be easier and more enjoyable to use. We will use the information you provide to learn about which version is the most effective.

What we will ask you to do

We will assign you to receive one of the special new versions of the EFP program.

No matter which special new version of the program you receive, you will be asked to complete 5 units during your participation. These 5 units are:

- Communicating with Your Child,
- Creating Structures and Rules,
- Giving Directions,
- Using Discipline and Consequences, and
- Using Time-Out

You will have 2 weeks to complete each unit. Each unit includes reading (articles, quick tips, and advice from experts), interactive exercises, watching brief videos, trying unit skills with your child, and telling us how you did when trying out unit skills. It should take about 30 minutes a week of your time to go through the unit content over 10 weeks.

We will ask you to

- Provide us with your contact information (name, phone number, email address and mailing address) and keep us updated of any changes.
- Give permission to receive email and text messages from the study.
- Complete 13 surveys as follows:
 - You would complete the first survey (about 40 minutes long) within six days of receiving access to the study website.
 - Complete 11 brief weekly surveys (most are about 10-15 minutes long; the week 11 one is about 20 minutes).
 - Complete a final survey during at week 25 (about 20 minutes long).

- The surveys will include questions about several topics:
 - Basic information about you and your family (e.g., age; number of children)
 - Your parenting style
 - Your child's behavior
 - Your stress and mental health
 - The EFP program
 - Your satisfaction with it
 - Your reasons for using it

Benefits of being in the study

Although we cannot guarantee that you will benefit from this study, we expect that you may find the website and activities fun and useful and that you may learn skills that will be helpful to you as a parent. The information we get from the study will help us make the website even better for parents.

Compensation for being in the study

It will not cost you anything to be part of the study. To thank you for your time, we will mail you a \$20 check after you complete the first survey. For the other surveys you complete, you will be given a choice for how you receive your thank you: either by a one-time use Amazon Gift code or a mailed check. You will get \$10 per survey for the brief surveys in weeks 1-10. When you complete the longer surveys at weeks 11 and 25, you will receive \$15. In total, you will receive \$150 if you finish all your surveys on time. If you decide to discontinue at any time, you will be paid for the surveys you have completed up to that point.

Important things you need to know

- There are no known risks associated with your participation in this research beyond those of everyday life.
- You will get a special version of the EFP program by participating in this study. We believe that it will be easier and more enjoyable to use. However, if you choose not to participate, then you can still access the original content from the Essentials for Parenting program on the Centers for Disease Control and Prevention website (<https://www.cdc.gov/parents/essentials/toddlersandpreschoolers/index.html>).
- Taking part of this study is completely your choice. The surveys will have questions about your parenting practices and behaviors, your feelings, and your opinions about the program. Some of the survey questions may feel uncomfortable, and you may decide not to answer any questions on the surveys that you don't want to answer. There is no penalty for stopping or skipping questions, and it won't affect any other benefits or services you would otherwise get.
- Your participation will be ended by the study team if you do not complete the first survey within six (6) days of receiving access to the study website.
- There is no consequence for requesting to withdraw from the study. After receiving your withdrawal request, you will receive a withdrawal confirmation message from the study. However, we will use the information that you have provided up to that point.
- If you withdraw from the study, then you will no longer be able to access the special study versions of the EFP program. However, you may still access the original program on the Centers for Disease and Control Prevention website (<https://www.cdc.gov/parents/essentials/toddlersandpreschoolers/index.html>)

- During your participation, you may be shown a Leaderboard concerning your use of the EFP program. This Leaderboard may show both real and simulated participants.
- We will take steps and precautions to protect your privacy. All project staff sign a confidentiality agreement. Your name and child's name will not be used in any research reports. We will assign a study ID to your information, and only a small number of study staff will have access to the connection between study IDs and actual names. All study information will be stored on secure servers at Westat. We will not sell or share information that can personally identify you with anyone.
- Your interactions with the EFPprogram will take place on a secure website. This will greatly reduce the risk of:
 - Identity theft, viruses, and SPAM.
 - Other parties accessing your information, or your computer, phone or tablet.
- A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website may include a summary of the results, but will never include information that can identify you. You can search this website at any time.
- Information about you collected for this study may be shared with other researchers, used for other research studies, or placed in a data repository. These studies may be similar to this study or completely different. We will remove all information that could personally identify you before sharing it.
- If you have questions about the study itself and what we are doing, a member of our study team can help you. For those questions, please contact us through the 'Contact Us' page of the website at < PUBLIC_SITE_URL >. The study's mailing address is: Attn: EFP Study 1600 Research Blvd. Rockville, MD 20850
- If you have a problem that a study team member couldn't help you resolve, please call Maeve Gearing, the Project Director, <<INSERT 800 # AND EXTENSION>>.
- For questions about your rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects, New York University, 665 Broadway, Suite 804, New York, NY 10012 at 212-998-4808 or ask.humansubjects@nyu.edu. Please refer to the study number IRB-FY2023-6896 when contacting the Committee.
- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena.
Exceptions include:
 - A federal, state, or local law requires disclosure.
 - Your explicit approval for the researchers to release your name and/or personally identifiable information.

Thank you for agreeing to participate! Click 'Next' to complete your consent.

Previous

Next

ONLINE CONSENT FORM, SCREEN 2:

Please check the box next to each part of the study, letting us know that you understand what your participation means. The first four boxes need to be checked for you to participate in the study.

I agree to provide the EFP study with my contact information (name, phone number, email address and mailing address) and will let you know if any change.

I give permission to receive email and text messages from the study.

I agree to complete 13 surveys over 11 weeks and at week 25.

I also agree to complete 5 Essentials for Parenting Toddlers and Preschoolers units over 10 weeks.

If you do not wish to participate, check the box below:

I no longer wish to participate.

<<BOXES 1-4 ARE REQUIRED TO BE CHECKED TO CONTINUE WITH CONSET. ADD SOFT ERROR MESSAGE POP-UP IF PARENT FORGOT TO CHECKBOXES 1—4. . MESSAGE TEXT: “PLEASE CHECK THE FIRST FOUR BOXES TO CONTINUE WITH YOUR CONSENT.”>>

<<AUTOMATICALLY GOES TO THE NEXT SCREEN>>

<<IF PARENT CHECKS, ‘I NO LONGER WISH TO PARTICIPATE.’ END CONSENT FORM AND SHOW THE FOLLOWING POP-UP MESSAGE, “WE ARE SORRY THAT YOU DO NOT WANT TO PARTICIPATE IN ALL PARTS OF THE ESSENTIALS FOR PARENTING TODDLERS AND PRESCHOOLERS (EFP) STUDY. FOR CDC’S GUIDELINES AND STRATEGIES ON HANDLING COMMON CHALLENGES IN PARENTING TODDLERS AND PRESCHOOLERS, PLEASE

VISIT<https://www.cdc.gov/parents/essentials/toddlersandpreschoolers/index.html> .”>>

ONLINE CONSENT FORM, SCREEN 3:

Please type your name below to say:

I have read the information in the presentation and on the previous page and I agree to take part in the Essentials for Parenting Toddlers and Preschoolers (EFP) Study:

First name:

Middle name (optional):

Last name:

Date: 2022-01-24 (NOTE, THIS IS AUTOMATICALLY SHOWN ON WEBSITE)

[Previous](#)

[Next](#)

ONLINE CONSENT FORM, SCREEN 4:

You have already agreed to receive email and text messages from the study. Please provide your contact information:

Cell phone number:

Re-enter your cell phone number for confirmation:

<<SOFT ERROR MESSAGE POP-UP IF CELL PHONE NUMBER ENTERED DOES NOT MATCH. MESSAGE TEXT: "THE CELL PHONE NUMBERS DO NOT MATCH. PLEASE CHECK THE NUMBER AND ENTER IT AGAIN."

Please provide your email address:

Re-enter your email address for confirmation:

<<SOFT ERROR MESSAGE POP-UP IF EMAIL ADDRESS ENTERED DOES NOT MATCH. MESSAGE TEXT: "THE EMAIL ADDRESSES DO NOT MATCH. PLEASE CHECK THE ADDRESS AND ENTER IT AGAIN."

Previous

Next

ONLINE CONSENT FORM, SCREEN 5:

Thank you for agreeing to participate in the Essentials for Parenting Toddlers and Preschoolers (EFP) Study!

Be sure our messages don't go into your spam folder! Tap to add EFP's phone number and email address to your Contacts.

Please note that only one parent from a family is allowed to sign up for the study and only once. Participants who sign up multiple times will be removed from the study, so please do not sign up for the study again.

A member of our study team *may* call you to verify your participation.

You will receive an email confirming your consent and enrollment. The email confirmation will provide you with a PIN that you can use to access the secure EFP website.

[Download PDF Copy](#)

<<LINK TO AUTO-GENERATED PDF CONSENT FORM,
PARENTS CAN CLICK ON AND PRINT FOR THEIR RECORDS>>

<<AUTOMATICALLY GOES TO NEXT SCREEN>>

ONLINE CONSENT FORM, SCREEN 6:

You may now close your browser. Thank you!

AUTO-GENERATED PDF CONSENT FORM ON THE FOLLOWING PAGES



Consent Form

Thank you for your interest in the Essentials for Parenting Toddlers and Preschoolers (EFP) study! You have already reviewed the study information and signed the online consent form. This is a PDF copy that you may print your records.

Purpose of the Study

The study is being led by New York University and Westat, a research firm, on behalf of the National Institutes of Health, also known as the NIH. We are looking for 800 parents of toddlers to help us learn how to best engage parents in the EFP online parenting program.

As a parent of an 18-to 36-month old, your input will help us make the website better. We will give you access to one of several special new versions of the EFP program that we believe will be easier and more enjoyable to use. We will use the information you provide to learn about which version is the most effective.

What we will ask you to do

We will assign you to receive one of the special new versions of the EFP program.

No matter which special new version of the program you receive, you will be asked to complete 5 units during your participation. These 5 units are:

- Communicating with Your Child,
- Creating Structures and Rules,
- Giving Directions,
- Using Discipline and Consequences, and
- Using Time-Out

You will have 2 weeks to complete each unit. Each unit includes reading (articles, quick tips, and advice from experts), interactive exercises, watching brief videos, trying unit skills with your child, and telling us how you did when trying out unit skills. It should take about 30 minutes a week of your time to go through the unit content over 10 weeks.

You have also agreed to the following:

- Provide us with your contact information (name, phone number, email address and mailing address) and keep us updated of any changes.
- Give permission to receive email and text messages from the study.
- Complete 13 surveys as follows:
 - You would complete the first survey (about 40 minutes long) within six days of receiving access to the study website.
 - Complete 11 brief weekly surveys (most are about 10-15 minutes long; the week 11 one is about 20 minutes).

- Complete a final survey during at week 25 (about 20 minutes long).
- The surveys will include questions about several topics:
 - Basic information about you and your family (e.g., age; number of children)
 - Your parenting style
 - Your child's behavior
 - Your stress and mental health
 - The EFP program
 - Your satisfaction with it
 - Your reasons for using it

Benefits of being in the study

Although we cannot guarantee that you will benefit from this study, we expect that you may find the website and activities fun and useful and that you may learn skills that will be helpful to you as a parent. The information we get from the study will help us make the website even better for parents.

Compensation for being in the study

It will not cost you anything to be part of the study. To thank you for your time, we will mail you a \$20 check after you complete the first survey. For the other surveys you complete, you will be given a choice for how you receive your thank you: either by a one-time use Amazon Gift code or a mailed check. You will get \$10 per survey for the brief surveys in weeks 1-10. When you complete the longer surveys at weeks 11 and 25, you will receive \$15. In total, you will receive \$150 if you finish all your surveys on time. If you decide to discontinue at any time, you will be paid for the surveys you have completed up to that point.

Important things you need to know

- There are no known risks associated with your participation in this research beyond those of everyday life.
- You will get a special version of the EFP program by participating in this study. We believe that it will be easier and more enjoyable to use. However, if you choose not to participate, then you can still access the original content from the Essentials for Parenting program on the Centers for Disease Control and Prevention website (<https://www.cdc.gov/parents/essentials/toddlersandpreschoolers/index.html>).
- Taking part of this study is completely your choice. The surveys will have questions about your parenting practices and behaviors, your feelings, and your opinions about the program. Some of the survey questions may feel uncomfortable, and you may decide not to answer any questions on the surveys that you don't want to answer. There is no penalty for stopping or skipping questions, and it won't affect any other benefits or services you would otherwise get.
- Your participation will be ended by the study team if you do not complete the first survey within six (6) days of receiving access to the study website.
- There is no consequence for requesting to withdraw from the study. After receiving your withdrawal request, you will receive a withdrawal confirmation message from the study. However, we will use the information that you have provided up to that point.
- If you withdraw from the study, then you will no longer be able to access the special study versions of the EFP program. However, you may still access the original program on the Centers for Disease and Control Prevention website (<https://www.cdc.gov/parents/essentials/toddlersandpreschoolers/index.html>)

- During your participation, you may be shown a Leaderboard concerning your use of the EFP program. This Leaderboard may show both real and simulated participants.
- We will take steps and precautions to protect your privacy. All project staff sign a confidentiality agreement. Your name and child's name will not be used in any research reports. We will assign a study ID to your information, and only a small number of study staff will have access to the connection between study IDs and actual names. All study information will be stored on secure servers at Westat. We will not sell or share information that can personally identify you with anyone.
- Your interactions with the EFPprogram will take place on a secure website. This will greatly reduce the risk of:
 - Identity theft, viruses, and SPAM.
 - Other parties accessing your information, or your computer, phone or tablet.
- A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website may include a summary of the results, but will never include information that can identify you. You can search this website at any time.
- Information about you collected for this study may be shared with other researchers, used for other research studies, or placed in a data repository. These studies may be similar to this study or completely different. We will remove all information that could personally identify you before sharing it.
- If you have questions about the study itself and what we are doing, a member of our study team can help you. For those questions, please contact us through the 'Contact Us' page of the website at < PUBLIC_SITE_URL >. The study's mailing address is: Attn: EFP Study 1600 Research Blvd. Rockville, MD 20850
- If you have a problem that a study team member couldn't help you resolve, please call Maeve Gearing, the Project Director, <<INSERT 800 # AND EXTENSION>>.
- For questions about your rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects, New York University, 665 Broadway, Suite 804, New York, NY 10012 at 212-998-4808 or ask.humansubjects@nyu.edu. Please refer to the study number IRB-FY2023-6896 when contacting the Committee.
- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena.
Exceptions include:
 - A federal, state, or local law requires disclosure.
 - Your explicit approval for the researchers to release your name and/or personally identifiable information.

Thank you for agreeing to participate!

Name

Signature Date