Document Cover Page

Official Title of the Study: Improving Parent-Child Interactions to Enhance Child Health

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Informed Consent to Participate in Research

Study Title:	Improving Parent-Child Interactions to Enhance Child Health
Research Investigator(s):	Dr. Sarah Domoff, Department of Psychology at CMU Dr. Larissa Niec, Department of Psychology at CMU Dr. Rachael Nelson, Department of Exercise and Health Sciences at CMU Dr. Julie Lumeng, University of Michigan Dr. Niko Kaciroti, University of Michigan
Investigator(s) Contact Information	Dr. Sarah Domoff: (989) 774-1072, domof1se@cmich.edu Dr. Larissa Niec: (989)-774-6471, niec1l@cmich.edu

Key Information
Participating in this study involves multiple phases and activities. The purpose of this study is to examine whether the PATCH program improves children's health. To address this purpose, you will answer questionnaires, have your and your child's height and weight measured, and participate in video recordings to assess your interactions with your child. You and your child will also receive a 13-week intervention (the PATCH program) either now or 10 months later. You will also complete the same questionnaires, height and weight measurement, and participate in video recordings two additional times. All of your data will be saved for later use.

Introductory Statement
Thank you for your interest in our study! This study will be looking at whether the PATCH Program helps children's health.

What is the purpose of this study?
The purpose of this study is to learn how we can help parents and children interact in ways that will improve children's health.

What will I do in this study?
You will spend about 2 hours at our clinic (the Center for Children, Families, and Communities, or CCFC). You will complete a series of questionnaires (approximately 25; these questionnaires ask about your child's health and behaviors, as well as your own health, experiences, and behaviors). You will also be part of a videotaped activity with your child. You will also be weighed and measured. You will also videotape your family

eating dinner for 3 nights. You and your child will also receive the PATCH Program either now or 10 months later. In 4 and 10 months from now, you will do the same things again. During the PATCH Program, you and your child will also be video-recorded throughout the program.

Every two months, you will receive a phone call to make sure we have the right contact information for you.

How long will it take me to do this?
About 10 months.

Are there any risks to me for participating in the study?
The researchers have tried to reduce the risks. You may still experience some risks related to participation. There is the risk that your personal information may be seen or heard by someone from outside the research team. To prevent this from happening, we store your information in a secure room in a locked office that only researchers have access to. We will keep your research data in a separate locked file from your name and other identifying information (e.g., address, date of birth) to reduce the risk of someone other than the researchers connecting the information to you. If research staff observes or hears about an event that makes us believe that your child or others have been or may be physically harmed, we may be required to report that information to the appropriate agencies. As with any research study, there may be additional risks that are unknown or unexpected.

What are the potential benefits of participating in the study?

You may have a better relationship with your child. You may feel less stress. Your child's behaviors may get better. You are receiving help free of charge.

Is there a different way for me to receive the benefits of this study?
You do not have to participate. If you don't participate, but want help for your child, we will help you find a provider (e.g., Listening Ear 989-386-2774 and Psychological Training and Consultation Center at CMU 989-774-3904).

Who beside the research team will know what I will do or say in this study (Confidentiality)?
Staff of Central Michigan University and government agencies who ensure the protection of human subjects in research may examine your records. Otherwise, no one will know what you say or do in this study. Any data under the investigator's control will, if disclosed, be presented in a manner that does not reveal your identity, except as may be required by law. The video and audio recordings will be kept on compact discs that will be stored in locked cabinets in a locked room of the Center for Children, Families, and Communities. If you provide consent for your data to be used in future studies, the compact discs will continue to be stored in this secure location after the study has

ended. Other non-video/audio-recorded data (i.e., paper measures) will not include personally identifiable information.

What will happen to my data after the study?
Any identifying information that can be removed will be removed from the data collected in this study. This includes destroying your contact information sheet. If you agree, after removal of identifiers, the information you provide may be used for future research studies. The only identifiable information that will be retained is the video and audio recordings we obtain during the assessment and intervention, as well as the video and audio recordings you provide from the family mealtime observation recordings. The video and audio recordings you provide may be used in training research assistants or shown during research presentations in the future. Details of the protection and use of this information is provided in the adjacent Consent for Future Use of Identifiable Information for Research. If you do not agree to broad consent, your video and audio recordings will be destroyed at the end of the study.

Recordings.

Participation in this study involves the collection of video and audio recordings. We will obtain video and audio recordings during the assessment; throughout the intervention; and as provided by you from the family mealtime observation recordings.

Will I receive any compensation for participation?

You may be compensated at most $205 over the duration of the study. Specifically, for each completed part of data collection (three times) you will receive up to $60:

-$30 for measures/observations completed at CCFC

-$10 for each video recording, collected up to 3 times ($30 max)

You will also get $5 every 2 months (for the 10 months of data collection) if you give us updated (or you confirm correct) contact information.

Is there a different way for me to receive this compensation of this study?

If you do not participate, there is not another way to receive the compensation.

Clinical Trials Information

ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. 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 Web site at any time.

Financial Support.

This work is financially supported by the National Institutes of Health. Central Michigan University and the investigators are being paid to conduct this research.

How can I contact a member of the study team for information about this study?

Please contact Dr. Sarah Domoff, (989) 774-6639, for any questions about this study.

How can I contact someone outside the research team for information about this study?

To talk to someone other than the researcher(s) about your rights as a research participant; obtain information; report a research-related injury; ask questions or discuss any concerns about this study; or you wish to offer input about this study, please contact (anonymously if you wish):

Central Michigan University Institutional Review Board
600 East Preston Street, Foust Hall 104
Mount Pleasant, MI 48859
Phone: (989) 774-6401
Email: IRB@cmich.edu

What happens if I refuse to participate or want to stop being in the study?
You are free to refuse to participate in this research project or to withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision not to participate will not affect your relationship with the institution(s) involved in this research project.

Please initial below if you consent to the following:

____ (initial here) I consent to being contacted by email for appointment scheduling and update calls. My preferred email is: _____

___ (initial here) I consent to research staff contacting contacts I list should research staff be unable to contact me using the contact information I provide.

___ (initial here) I consent to research staff contacting me via social media if they are unable to reach me via phone call or postal address mailing.

___ (initial here) I consent to being contacted every 2 months during the study to provide updated contact information.

Statement of Consent
My signature below indicates that I am 18 years of age or older and all my questions have been answered. I consent to participate in the project as described above.

Name of Participant: _____

Signature: _____

Date: _____

You will be given a copy of this form to keep for your records.

Statement of Person Obtaining Consent
I have discussed with this participant or LAR the procedure(s) described above and the risks involved in this research. I believe he/she understands the contents of this consent document and is competent to give legally effective and informed consent.

Name: _____

Signature: _____

Date: _____

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Parent/Guardian Consent Form

Study Title: Improving Parent-Child Interactions to Enhance Child Health

Research Investigators' Names and Departments:

Dr. Sarah Domoff, Department of Psychology at CMU
Dr. Larissa Niec, Department of Psychology at CMU
Dr. Rachael Nelson, Department of Exercise and Health Sciences at CMU
Dr. Julie Lumeng, University of Michigan
Dr. Niko Kaciroti, University of Michigan

Contact Information:
Dr. Sarah Domoff: (989) 774-1072, domof1se@cmich.edu
Dr. Larissa Niec: (989)-774-6471, niec1l@cmich.edu

Introductory Statement.
Thank you for your interest in our study! This study will be looking at whether the PATCH Program helps children's health.

What is the purpose of this study?
The purpose of this study is to learn how we can help parents and children interact in ways that will improve children's health.

What will my child/ward do in this study?
Your child will spend about 2 hours at our clinic (the Center for Children, Families, and Communities, or CCFC) with you. Your child will be part of a videotaped activity with you. Your child will also be weighed and measured. You will also videotape your child eating dinner for 3 nights. Your child will also be videotaped during the intervention portion (i.e., the PATCH program) of this study. Your child will wear a device on their wrist for seven days. Your child will remove the device when he/she is bathing. You and your child will also receive the PATCH Program either now or 10 months later. In 4 and 10 months from now, your child will do the same things again.

How long will it take my child/ward to do this?
About 10 months.

Are there any risks of participating in the study?

The researchers have tried to reduce the risks. You may still experience some risks related to participation. There is the risk that your personal information may be seen or heard by someone from outside the research team. To prevent this from happening, we store your information in a secure room in a locked office that only researchers have access to. We will keep your research data in a separate locked file from your name and other identifying information (e.g., address, date of birth) to reduce the risk of someone other than the researchers connecting the information to you. If research staff observes or hears about an event that makes us believe that your child or others have been or may be physically harmed, we may be required to report that information to the appropriate agencies. As with any research study, there may be additional risks that are unknown or unexpected.

What if my child/ward is injured while participating in this study?
If your child/ward is injured while participating in the study, CMU personnel will assist in obtaining emergency care. If the child is covered by insurance for medical care, the insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of those paid by the child's insurance, including deductibles, will be your responsibility. CMU does not provide financial compensation for the disability, pain, or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you or your child/ward may have. You may contact Dr. Domoff at (989) 774-1072 with any questions or to report injury.

What are the benefits of participating in the study?
Your child may not receive any benefits.

Is there a different way for my child/ward to receive the benefits of this study?
You do not have to participate. If you don't participate, but want help for your child, we will help you find a provider (e.g., Listening Ear 989-386-2774 and Psychological Training and Consultation Center at CMU 989-774-3904).

Clinical Trials Information
ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by U.S. 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 Web site at any time.

Will anyone know what my child/ward does or says in this study (Confidentiality)?
Staff of Central Michigan University and government agencies who ensure the protection of human subjects in research may examine your records. Otherwise, no one will know what you say or do in this study. Any data under the investigator's control will, if disclosed, be presented in a manner that does not reveal your identity, except as may be required by law. The video and audio recordings will be kept on compact discs that will be stored in locked cabinets in a locked room of the Center for Children, Families, and Communities. If you provide consent for your data to be used in future studies, the compact discs will continue to be stored in this secure location after the study has ended.

Other non-video/audio-recorded data (i.e., paper measures) will not include personally identifiable information after the conclusion of this study.

What will happen to my data after the study?
Any identifying information that can be removed will be removed from the data collected in this study. This includes destroying your contact information form. If you agree, after removal of identifiers, the information you provide may be used for future research studies. The only identifiable information that will be retained is the video and audio recordings we obtain during the assessment and intervention, as well as the video and audio recordings you provide from the family mealtime observation recordings. The video and audio recordings you provide may be used in training research assistants or shown during research presentations in the future. Details of the protection and use of this information is provided in the adjacent Consent for Future Use of Identifiable Information for Research. If you do not agree to broad consent, your video and audio recordings will be destroyed at the end of the study.

Will anyone outside of the research team have access to my child's collected data?
Central Michigan University staff and state or federal agency officials who ensure the protection of human subjects in research may access your child's records while carrying out their official duties or as required by law.

Will I or my child/ward receive any compensation for participation?

Your child will not receive any compensation for their participation in the study.
You may be compensated at most $205 over the duration of the study. Specifically, for each completed part of data collection (three times) you will receive up to $60:

-$30 for measures/observations completed at CCFC
-$10 for each video recording, collected up to 3 times ($30 max)

You will also get $5 every 2 months (for the 10 months of data collection) if you give us updated (or you confirm correct) contact information.

Is there a different way for me to receive this compensation of this study?
If you do not participate, there is not another way to receive the compensation.

How can I contact a member of the study team for information about this study?
Please contact Dr. Sarah Domoff, (989) 774-1072, for any questions about this study.

Who can I contact outside of the study team for information about this study?
If you have questions about your rights as a research participant, wish to obtain information or report a case of research-related injury, ask questions, discuss any concerns about this study, or wish to offer input about this study with someone other than the researcher(s), please contact the:

Central Michigan University Institutional Review Board

600 East Preston Street
Foust Hall 104
Mount Pleasant, MI 48859
Phone: (989) 774-6401
Email: IRB@cmich.edu

You are free to refuse to allow your child/ward to participate in this research project or to withdraw your permission and discontinue your child's participation at any time without penalty or loss of benefits to which your child/ward is otherwise entitled. Your child's participation will not affect your relationship with the institution(s) involved in this research project.

My signature below indicates that I am 18 years of age or older and all my questions have been answered. A copy of this form has been given to me.
I agree to allow my child/ward to participate in the project as described above.

Name of Subject: _____

Name of Parent or Guardian: _____

Signature of Parent or Guardian: _____

Date: _____

For the Research Investigator. I have discussed with this parent/guardian the procedure(s) described above and the risks involved in this research. I believe he/she understands the contents of this document and is competent to give legally effective and informed permission.

Name: _____

Signature: _____

Date: _____

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Consent for Future Use of Identifiable Video and Audio Information in Research

Study Title:	Improving Parent-Child Interactions to Enhance Child Health
Research Investigator(s):	Dr. Sarah Domoff, Department of Psychology at CMU Dr. Larissa Niec, Department of Psychology at CMU Dr. Rachael Nelson, Department of Exercise and Health Sciences at CMU Dr. Julie Lumeng, University of Michigan Dr. Niko Kaciroti, University of Michigan
Investigator(s) Contact Information	Dr. Sarah Domoff: (989) 774-1072, domof1se@cmich.edu Dr. Larissa Niec: (989)-774-6471, niec1l@cmich.edu

Introductory statement.
This consent provides information about the identifiable information that will be stored past the duration of the current study. Signing this consent allows us to store data for future research projects. The only identifiable information being stored from the current study will be the audio and video recordings obtained during the assessment, intervention, and family mealtime observations (which you may provide). The recordings may be used for future projects investigating other aspects of parenting practices and child behavior, without your later consent. They may be used for training research assistants in the future, and may be shown during research presentations (again, without you providing later consent).

Are there any risks to me for consenting for my recordings to be used for future use?
There are minimal risks in consenting for your recordings to be stored for future use. Because your recordings may be shown to research assistants and at conferences in the future, there is the risk that your image or voice may be seen or heard by someone who knows you.

What are the potential benefits of participating in the study?
There are no potential benefits for providing consent for future use of your information.

Confidentiality
The compact discs containing the video and audio recordings will be stored in a locked cabinet in a locked room of the Center for Children, Families and Communities. To protect the confidentiality of your stored recordings, no other information about you will be maintained, and we will never attempt to connect the stored recordings to your name or other identifying information. Although someone who knows you might see a presentation of the recordings, the chance of this is very small.

Your participation is voluntary
Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

Uses of your information
The only identifiable information that will be stored past the conclusion of the study will be the video and audio recordings of you and your child. This is identifiable because it includes your images and voices, and we may record you saying your child's name or other information. This video and audio will be stored in the Center for Children, Families, and Communities. The recordings may be used in future studies of parenting practices and child behavior. The recordings may be used for training of research assistants in the future. The recordings may be used for presentations at conferences.

How long will my information be stored?
There is no set end date for when this information will be destroyed.

Future uses.
You will not be informed of the details of any specific research studies that might be conducted using your identifiable private information, including the purposes of the research. You may have chosen to not consent to some of these specific research studies. However, our research typically has the purpose of informing parent-child prevention and intervention programs. Additionally, the recordings may be used for training of research assistants in the future. The recordings may be used for presentations at conferences. We will not share the recordings with other researchers outside of CMU.

How can I contact someone for information about this study?
Please contact Dr. Sarah Domoff, (989) 774-1072, for any questions about this study.

To talk to someone other than the researcher(s) about your rights as a research participant; discuss the storage and use of your identifiable private information; obtain information; report a research-related injury; ask questions or discuss any concerns about this study; or you wish to offer input about this study, please contact (anonymously if you wish):

Central Michigan University Institutional Review Board
600 East Preston Street, Foust Hall 104
Mount Pleasant, MI 48859
Phone: (989) 774-6401
Email: IRB@cmich.edu

What happens if I refuse to participate or want to stop being in the study?
You are free to refuse to give broad consent. However, you will not be able to withdraw your consent after the current study is over. Your decision not to participate will not affect your relationship with the institution(s) involved in this research project.

Statement of Consent
My signature below indicates that I am 18 years of age or older and all my questions have been answered. I consent to participate in the project as described above.

_____	_____	_____
Participant's printed name	Participant signature	Date

You will be given a copy of this form to keep for your records.

Statement of Person Obtaining Consent
I have discussed with this participant or LAR the procedure(s) described above and the risks involved in this research. I believe he/she understands the contents of this consent document and is competent to give legally effective and informed consent.

_____	_____	_____
Investigator's printed name	Investigator signature	Date