Official Title: The PRO-Parenting Study: Helping Parents Reduce Behavior Problems in Preschool Children with Developmental Delay

Brief Title: Partnerships in Research for Optimizing Parenting (PRO-Parenting Project)

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UNIVERSITY OF OREGON

Consent for Research Participation

Title:	Partnerships in Research for Optimizing Parenting (PRO-Parenting Project)
Sponsor:	National Institutes of Health, NICHD
Researcher(s):	Laura Lee McIntyre, PhD, University of Oregon
	Cameron Neece, PhD, Loma Linda University
Researcher Contact Info:	541-346-5123
	llmcinty@uoregon.edu

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose.** The purpose of this research is to compare two interventions aimed at increasing parental well-being and improving parenting skills in order to ultimately improve child behavior outcomes for children with developmental disability. The primary intervention we will be using is a behavioral parent training (BPT) program where you will learn parenting strategies to enhance your relationship with your child as well as help manage your child's behavior problems. The BPT program will be supplemented with either a mindfulness intervention or an educational program. We are interested in seeing how the addition of either the mindfulness or educational programs affect both immediate and longer-term outcomes for your family.
- **Duration.** It is expected that your participation will last up to 18 months.
- **Procedures and Activities.** You will be asked to participate in a pre-intervention assessment which lasts 60-90 minutes and includes an interview, paper surveys, and a video-taped play activity with your child. During this phase of the project we will also conduct a brief developmental evaluation of your child, which takes about one hour to complete. You will then be randomly assigned to receive one of two interventions, each requiring weekly 2-hour group meetings for 16 weeks. After the final group meeting, you will be asked to participate in a post-intervention assessment, which is very similar to the one you would complete prior to the intervention. You will repeat this post-intervention assessment again 6 months and 12 months after groups have finished meeting. In addition, teachers will be asked to complete a short questionnaire packet about your child at 4 time points.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include privacy and psychological risks. Some of the questions in the parent questionnaires may be

perceived as too personal (e.g., questions about the marriage), and some young children may show mild frustration, distress, or boredom with research tasks. Although precautions are taken to protect the privacy of your data, there is always a risk of a confidentiality breach.

- **Benefits**. Some of the benefits that may be expected include possible reduction in parental stress, possible improvement in parenting behaviors, and possible decline in children's behavior problems. In addition, as part of the study you will have access to research staff with expertise in child development who will be able to answer your questions about your child's development, need for services, and local resources.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Who is conducting this research?

The researchers, Dr. Laura Lee McIntyre from University of Oregon and Dr. Cameron Neece from Loma Linda University, are asking for your consent to this research.

Why is this research being done?

The purpose of the research is to compare two interventions aimed at increasing parental well-being and improving parenting skills in order to ultimately improve child behavioral outcomes. The primary intervention we will be using is a behavioral parent training (BPT) program where you will learn parenting strategies to enhance your relationship with your child as well as help manage your child's behavior problems. The BPT program will be supplemented with a mindfulness intervention or an educational program. We are interested in seeing how the addition of either the mindfulness or educational programs affect both immediate and longer-term outcomes for your family.

The rationale for this study is drawn from research, which suggests that parents of children with developmental delays often experience heightened parenting stress, compared to parents of typically developing children. High levels of parenting stress may affect your family over time and decrease the effectiveness of interventions. The goal of this project is to understand how to make our interventions more effective for families with children with developmental delays. You are being asked to participate because you are a parent of a child who has been identified as having developmental concerns. About 300 families will take part in this research.

How long will I be in this research?

We expect that your participation will last up to 18 months. If you agree to be in this research, your family's participation will include four home visits and one laboratory visit over the course of 18 months. Each visit is 60-90 minutes long. Because we are interested in learning about the effect of the intervention on you and your child across time, we are seeking your participation from the pre-intervention assessment until the completion of the follow-up assessments (see details below).

What happens if I agree to participate in this research?

Participation in this study involves the following:

Pre-Intervention Assessment: An initial enrollment interview will be conducted at the first home visit. This consent form will be mailed to you before the visit. Additionally, you will be mailed a packet of questionnaires that should be completed by the participating parent(s) prior to the first home assessment.

The pre-intervention visit will consist of three parts. First, you will be given an opportunity to ask further questions about the study and then we will obtain your consent. Next, you will engage in an observational play activity with your child for about 18 minutes. This observation will be videotaped with your consent. After the observation, you will be interviewed to obtain basic demographic and family background information. Any remaining questionnaires

regarding parental attitudes, family functioning, and perceptions of your child will be also completed. While you are being interviewed, your child will participate in a brief developmental evaluation.

Once you complete the pre-intervention visit, we will let you know your group assignment. You will be randomly assigned to either the Behavioral Parent Training – Mindfulness (BPT-M) group or the Behavior Parent Training – Education (BPT-E) group. Both intervention groups will begin at the same time and last 16 weeks. We cannot guarantee your assignment to a particular group. Therefore, in consenting to participation, you are agreeing to participate in either group. You will receive a call from our scheduler with your group assignment.

The Intervention: Parents randomly assigned to the BPT-M group will receive six sessions of Mindfulness-Based Stress Reduction followed by the 10-week BPT intervention described below. The MBSR component of the BPT-M intervention will include six weekly 2-hour group sessions, 30–45 minutes of daily home practice guided by instructional audio CDs and an MBSR parent workbook. Formal mindfulness exercises aim to increase the capacity for mindfulness (present-moment awareness with a compassionate, nonjudgmental stance) and include a body scan, mindful yoga, and sitting meditation. In the sessions, participants practice formal mindfulness exercises and ask questions relating to the practice of mindfulness in everyday life, and the instructor provides didactic instruction on stress physiology and using mindfulness for coping with stress in daily life.

Parents randomly assigned to the BPT-E group will receive six sessions of education about children with developmental disabilities. The BPT-E group will also consist of 6-weekly 2-hour education sessions where families will gain information regarding their child's development, disability, and associated considerations. Each week has a general topic for discussion. Topics include Preparing for Individualized Education Plan (IEP) meetings, Navigating the Regional Center and Developmental Service Agencies, Communicating with Teachers, Advocacy, Sibling Issues, and Community Resources. At the start of each session, group leaders provide some educational material on the topic. Parents then break up into pairs for small group discussion followed by a larger group discussion and questions. Following the 6-week educational intervention, families will receive the same 10-week Behavioral Parent Training intervention described below.

All participants will then receive the Incredible Years Parent Training-Developmental Disabilities modified intervention. The IYPT-DD intervention is 10 weeks in duration, with each weekly session lasting 2 hours. Each weekly session is structured around videotape vignettes and uses discussion, role-playing, modeling, and feedback techniques to create an effective learning environment for the parenting skills that are taught. Parents are given weekly homework assignments and have the opportunity to practice their skills both inside and outside of intervention sessions. Parent(s) are expected to attend all sessions in order to maximize the benefit of the intervention.

Post-Intervention Assessment: After the completion of the intervention, you will be asked to schedule a second home assessment. A similar set of questionnaires will be mailed to your home that we ask you to complete prior to the lab visit. During the post-intervention home visit, you and your child will complete a similar play activity for 20 minutes. This task will be recorded with your permission.

Follow-Up Assessments: Six months after the groups have finished, you will be asked to schedule a home visit for a follow-up assessment to see how you and your child are doing. At this assessment, again you will be asked to complete a packet of questionnaires prior to the visit and will participate in a 20-minute play activity. The task will be recorded with your permission. This same process will be repeated 12 months after groups have finished (6 months after the first follow-up).

Teacher Assessment: Additionally, because we feel that input from each child's teacher is a critical element in gaining a complete picture of the child, we will be collecting data from your child's teacher about your child's behavior. To do this, we will collect the contact information for your child's teacher from you and mail a consent form and short questionnaire to the teacher. She/ he will complete the survey and mail it back to the research team prior to the intervention. Your child's teacher will be paid $25 for completing this questionnaire. We plan to collect these teacher assessments at 4 time points: prior to the intervention, at the end of the intervention, at 6 months, and at 12 months after the intervention is completed. Teachers will be paid each time they return a teacher survey.

We will tell you about any new information that may affect your willingness to continue participation in this research.

What happens to the information collected for this research?

Information collected for this research will be used to help researchers, clinicians, and educators understand how to make interventions more effective for families with children with developmental delays.

We are likely to publish or present the results of this research. However, your name will not be used in any published reports or conference presentations about this study. We will keep your name and other identifying information confidential. Personal identifiers will be removed from data and replaced with an ID number prior to data storage and analysis.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected. Measures we take include:

- conducting research in private settings (such as your home or our research center);
- removing all personal identifiers from data prior to storage and analysis

We will take measures to protect the security of all your personal information, but we can never fully guarantee confidentiality of all study information. Measures we take include:

- storing all original data in locked files in locked offices in our research lab;
- coding all electronic information and storing it in a password protected file on a secure server; and
- strictly limiting access to video tape recordings to research staff involved in the project. These recordings do not include participants' identifying information and are assigned a unique participant identification number. These recordings are kept in locked files and locked offices, with strict limits on who can access them. Video recordings are used for training and research purposes only and will not be used for other purposes without your written consent.

All the information collected from the laboratory/home visits and intervention, as well as from the questionnaires will remain confidential and will be disclosed only with your permission or as required by law. Under Oregon law, the privilege of confidentiality does not extend to information about sexual or physical abuse of children or the elderly, or in the event of suicide risk. If any member of the project staff has or is given such information, he or she is required to report it to authorities. The obligation to report includes alleged or probable abuse as well as known abuse.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in a federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse, but not for federal, state, or local civil, administrative, legislative, or other proceedings); if you have consented to the disclosure; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect or harm to self and others.

Individuals and organization that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information. These individuals and organizations include: the Institutional Review Board that reviewed this research; the National Institute for Child Health and Human Development; and University of Oregon auditors.

Seven years after completion of this study, all consent documents will be destroyed.

What are the risks if I participate in this research?

The risks or discomforts of participating in this research include privacy and psychological risks.

We anticipate few discomforts or risks will be involved in your family's participation in this project. In fact, in our experience, families usually very much enjoy their participation. Nevertheless, some of the questions in the questionnaires do address personal information about you and your family and might be considered an invasion of your privacy (e.g., questions about the marriage). Also, some young children may show mild frustration or distress during the home situations involving you placing demands on your child (e.g. asking them to clean up). Your child may also face some mild frustration / boredom during the lab visit during the developmental assessment due to its length (approximately 40-60 minutes). And even though we take many precautions to protect your data, there is always a possibility of a breach of confidentiality. For these mild or minor risks, a member of our staff will always be available to address your questions or concerns.

What are the benefits of participating in this research?

You may or may not benefit from participating in this research. Potential benefits to your family following the intervention include: (1) possible reduction in parental stress, (2) possible improvement in parenting behaviors, and (3) possible decline in children's behavior problems. In addition, you will receive a short summary of your child's current and previous behavioral functioning based on study assessments after completion of the 12-month follow-up visit. In addition, as part of the study you will have access to a research staff with expertise in child development who will be able to answer your questions about your child's development, need for services, and local resources.

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision to participate or withdraw from this study will have no effect on other services you may be receiving (e.g., from Clackamas ESD or from the University of Oregon) and will not affect your relationship with the researchers or the University of Oregon.

In addition, you may review all video and/or audio tapes that are made during any visit, and you have the right to request that any such tape be erased in full or in part.

If you decide to withdraw from the research study, please contact [redacted] to request that your information not be used for research.

Will it cost me money to take part in this research?

There is no cost to you for participating in this study.

Will I be paid for participating in this research?

For taking part in this research, you may be paid up to a total of $400 (paid via check at time of each assessment). Your compensation will be broken down as follows:

- $50 pre-intervention family assessment (which includes interview, questionnaires, and family play task);
- $50 pre-intervention developmental assessment of child;
- $75 post-intervention assessment (similar to the pre-intervention assessment);
- $100 6-month follow-up assessment (similar to the pre-intervention assessment);and
- $125 12-month follow-up assessment (similar to the pre-intervention assessment).

If your family withdraws from the study before completion, you will not receive the remaining payments. In the event that a visit needs to be rescheduled, your family will be compensated upon completion of the rescheduled visit.

Your child's teacher will also be paid up to a total of $100 (also paid via check at time of each assessment). Your child's teacher will receive $25 each time he/she completes the questionnaire about your child:

- $25 pre-intervention assessment;
- $25 post-intervention assessment;
- $25 6-month follow-up assessment;
- $25 12-month follow-up assessment.

Please be aware that compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separately from research data. If you receive $600 or more in a calendar year, you may be contacted to provide additional information for tax reporting purposes.

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

[redacted]

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510

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STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

I consent to participate in this study.

_____	_____	_____
Name of Adult Participant	Signature of Adult Participant	Date

Information you provided during the phone screening regarding parenting stress will be used in the study.

Initial the space below if you consent to the use of this information.

___ I agree to the use of information collected during the phone screening.

As described above, your family will be audio/ video recorded during the home play tasks and your child will be recorded during the developmental evaluation at the lab visit. These recordings will only be used for research purposes. Families may still participate in the research study even if they do not consent to the use of audio/ video recording.

Initial the space below if you consent to the use of audio/ video recording as described.

___ I agree to the use of audio/video recording.

As described above, we would like to contact your child's teacher to get his/ her perception of your child's behavior. Please provide your child's teacher's name and contact information below.

_____	_____
Teacher Name	Teacher Email Address

_____

Teacher Address

Researcher Signature (to be completed at time of informed consent)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

Name of Research Team Member	Signature of Research Team Member	Date

Official Title: The PRO-Parenting Study: Helping Parents Reduce Behavior Problems in Preschool Children with Developmental Delay

Brief Title: Partnerships in Research for Optimizing Parenting (PRO-Parenting Project)

NCT Number: NCT03599648

Document Type: Parent Informed Consent Form (version used with cohorts after start of COVID-19 pandemic)

Document Date: 10/8/2020

UNIVERSITY OF OREGON

Consent for Research Participation

Title:	Partnerships in Research for Optimizing Parenting (PRO-Parenting Project)
Sponsor:	National Institutes of Health, NICHD
Researcher(s):	Laura Lee McIntyre, PhD, University of Oregon
	Cameron Neece, PhD, Loma Linda University
Researcher Contact Info:	541-346-5123
	llmcinty@uoregon.edu

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Key Information for You to Consider

- **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose.** The purpose of this research is to compare two interventions aimed at increasing parental well-being and improving parenting skills in order to ultimately improve child behavior outcomes for children with developmental disability. The primary intervention we will be using is a behavioral parent training (BPT) program where you will learn parenting strategies to enhance your relationship with your child as well as help manage your child's behavior problems. The BPT program will be supplemented with either a mindfulness intervention or an educational program. We are interested in seeing how the addition of either the mindfulness or educational programs affect both immediate and longer-term outcomes for your family.
- **Duration.** It is expected that your participation will last up to 18 months.
- **Procedures and Activities.** You will be asked to participate in a pre-intervention assessment which will last about 3 hours and will be spread out over 3 separate Zoom sessions. This assessment includes interviews, a paper survey, and a video-recorded play activity with your child. During this phase of the project we will also conduct the parent portion of a brief developmental evaluation of your child, which takes about 40 minutes to complete. You will then be randomly assigned to receive one of two interventions, each requiring weekly 2-hour group meetings via Zoom for 16 weeks. After the final group meeting, you will be asked to participate in a post-intervention assessment, which is very similar to the one you would complete prior to the intervention. You will repeat this post-intervention assessment again 6 months and 12 months after groups have finished meeting. In addition, teachers will be asked to complete a short questionnaire packet about your child at 4 time points. If physical distancing restrictions are lifted before the end of the study period, and we are able to see you and your child safely without masks, we will

conduct a brief developmental evaluation of your child in our research office; it will take about one hour to complete. If these restrictions are not lifted before the end of the study period, we will forgo this specific aspect of data collection. Finally, in addition to the activities listed above, you will be asked to complete a survey about your family's experiences during the covid-19 pandemic at two points in time.

- **Risks.** Some of the foreseeable risks or discomforts of your participation include privacy and psychological risks. Some of the questions in the parent questionnaires may be perceived as too personal (e.g., questions about the marriage), and some young children may show mild frustration, distress, or boredom with research tasks. Although precautions are taken to protect the privacy of your data, there is always a risk of a confidentiality breach.
- **Benefits**. Some of the benefits that may be expected include possible reduction in parental stress, possible improvement in parenting behaviors, and possible decline in children's behavior problems. In addition, as part of the study you will have access to research staff with expertise in child development who will be able to answer your questions about your child's development, need for services, and local resources.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Who is conducting this research?

The researchers, Dr. Laura Lee McIntyre from University of Oregon and Dr. Cameron Neece from Loma Linda University, are asking for your consent to this research.

Why is this research being done?

The purpose of the research is to compare two interventions aimed at increasing parental well-being and improving parenting skills in order to ultimately improve child behavioral outcomes. The primary intervention we will be using is a behavioral parent training (BPT) program where you will learn parenting strategies to enhance your relationship with your child as well as help manage your child's behavior problems. The BPT program will be supplemented with a mindfulness intervention or an educational program. We are interested in seeing how the addition of either the mindfulness or educational programs affect both immediate and longer-term outcomes for your family.

The rationale for this study is drawn from research, which suggests that parents of children with developmental delays often experience heightened parenting stress, compared to parents of typically developing children. High levels of parenting stress may affect your family over time and decrease the effectiveness of interventions. The goal of this project is to understand how to make our interventions more effective for families with children with developmental delays. You are being asked to participate because you are a parent of a child who has been identified as having developmental concerns. About 300 families will take part in this research.

How long will I be in this research?

We expect that your participation will last up to 18 months. If you agree to be in this research, your family's participation will include a series of 2-3 virtual home visits at four points in time and one research office visit over the course of 18 months. Each visit is about one hour long. Because we are interested in learning about the effect of the intervention on you and your child across time, we are seeking your participation from the pre-intervention assessment until the completion of the follow-up assessments (see details below).

What happens if I agree to participate in this research?

Participation in this study involves the following:

Pre-Intervention Assessment:

The pre-intervention assessment will consist of a packet of questionnaires mailed to your home and three hour-long virtual home visits conducted via Zoom. The packet of questionnaires should be completed by the participating parent(s) prior to the completion of the virtual home assessments.

- Virtual home visit #1: This visit is only for the parent/ caregiver. A member of our research staff will go over this consent document with you and give you an opportunity to ask further questions about the study. Once you provide consent to continue with the visit, the staff member will interview you in order to obtain basic demographic and family background information. She/ he will then provide information about what to expect at the next visit, help you to prepare, and answer any questions you might have. Soon after this visit is completed, you will receive a box of toys and other materials required for the second visit.
- Virtual home visit #2: This visit is for the parent/ caregiver and child. Research staff will confirm that you received the box of toys and other materials, and provide additional instructions about how and when to use these materials. You will then engage in a play activity with your child for about 15 minutes. This observation will be recorded via Zoom with your consent.
  At the end of this visit we will let you know your group assignment. You will be randomly assigned to either the Behavioral Parent Training – Mindfulness (BPT-M) group or the Behavior Parent Training – Education (BPT-E) group. Both intervention groups will begin at the same time and last 16 weeks. We cannot guarantee your assignment to a particular group. Therefore, in consenting to participation, you are agreeing to participate in either group on the designated day of week.
- Virtual home visit #3: This visit is only for the parent/ caregiver and is an opportunity for you to meet one of the Family Consultants who will be leading the parent groups. The family consultant will use this opportunity to learn more about you and your child, and will complete a few remaining questionnaires with you, including one regarding your family's experiences during the Covid-19 pandemic.

The Intervention: Parents randomly assigned to the BPT-M group will receive six sessions of Mindfulness-Based Stress Reduction followed by the 10-week BPT intervention described below. The MBSR component of the BPT-M intervention will include six weekly 2-hour group sessions, 30–45 minutes of daily home practice guided by instructional audio CDs and an MBSR parent workbook. Formal mindfulness exercises aim to increase the capacity for mindfulness (present-moment awareness with a compassionate, nonjudgmental stance) and include a body scan, mindful yoga, and sitting meditation. In the sessions, participants practice formal mindfulness exercises and ask questions relating to the practice of mindfulness in everyday life, and the instructor provides didactic instruction on stress physiology and using mindfulness for coping with stress in daily life.

Parents randomly assigned to the BPT-E group will receive six sessions of education about children with developmental disabilities. The BPT-E group will also consist of 6-weekly 2-hour education sessions where families will gain information regarding their child's development, disability, and associated considerations. Each week has a general topic for discussion. Topics include Preparing for Individualized Education Plan (IEP) meetings, Navigating the Regional Center and Developmental Service Agencies, Communicating with Teachers, Advocacy, Sibling Issues, and Community Resources. At the start of each session, group leaders provide some educational material on the topic. Parents then break up into pairs for small group discussion followed by a larger group discussion and questions. Following the 6-week educational intervention, families will receive the same 10-week Behavioral Parent Training intervention described below.

All participants will then receive the Incredible Years Parent Training-Developmental Disabilities modified intervention. The IYPT-DD intervention is 10 weeks in duration, with each weekly session lasting 2 hours. Each weekly session is structured around videotape vignettes and uses discussion, role-playing, modeling, and feedback techniques to create an effective learning environment for the parenting skills that are taught. Parents are given weekly homework assignments and have the opportunity to practice their skills both inside and outside of intervention sessions. All sessions of each parent group will be held on Zoom. Parent(s) are expected to attend all sessions in order to maximize the benefit of the intervention.

Post-Intervention Assessment: After the completion of the intervention, you will be asked to schedule a post-intervention assessment. This assessment will consist of a packet of questionnaires mailed to your home, a brief survey completed online, and two hour-long virtual home visits conducted via Zoom. The two hour-long virtual home visits will be identical to visits #1 and #2 of the Pre-Intervention Assessment. The play task will be recorded with your permission.

Follow-Up Assessments: Six months after the groups have finished, you will be asked to schedule a a follow-up assessment to see how you and your child are doing. At this assessment, you will again be asked to complete a packet of questionnaires and 2 hour-long virtual home visits conducted via Zoom. The two hour-long virtual home visits will be identical to visits #1 and #2 of the Pre-Intervention Assessment.
The play task will be recorded with your permission. This same process will be repeated 12 months after groups have finished (6 months after the first follow-up).

Teacher Assessment: Additionally, because we feel that input from each child's teacher is a critical element in gaining a complete picture of the child, we will be collecting data from your child's teacher about your child's behavior. To do this, we will collect the contact information for your child's teacher from you and email a consent form and link to short questionnaire to the teacher. She/ he will complete the survey online prior to the intervention. Your child's teacher will be paid $25 for completing this questionnaire. We plan to collect these teacher assessments at 4 time points: prior to the intervention, at the end of the intervention, at 6 months, and at 12 months after the intervention is completed. Teachers will be paid each time they return a teacher survey.

We will tell you about any new information that may affect your willingness to continue participation in this research.

What happens to the information collected for this research?

Information collected for this research will be used to help researchers, clinicians, and educators understand how to make interventions more effective for families with children with developmental delays.

We are likely to publish or present the results of this research. However, your name will not be used in any published reports or conference presentations about this study. We will keep your name and other identifying information confidential. Personal identifiers will be removed from data and replaced with an ID number prior to data storage and analysis.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected. Measures we take include:

- conducting research in private settings (such as your home or our research center or on Zoom by using the HIPPA-compliant version of Zoom that utilizes additional layers of encryption);
- removing all personal identifiers from data prior to storage and analysis

We will take measures to protect the security of all your personal information, but we can never fully guarantee confidentiality of all study information. Measures we take include:

- storing all original data in locked files in locked offices in our research lab;
- coding all electronic information and storing it in a password protected file on a secure server; and
- strictly limiting access to video recordings to research staff involved in the project. These recordings do not include participants' identifying information and are assigned a unique participant identification number. These recordings are kept in locked files and locked offices, with strict limits

on who can access them. Video recordings are used for training and research purposes only and will not be used for other purposes without your written consent.

All the information collected from the research laboratory, virtual home visits, intervention, and questionnaires will remain confidential and will be disclosed only with your permission or as required by law. Under Oregon law, the privilege of confidentiality does not extend to information about sexual or physical abuse of children or the elderly, or in the event of suicide risk. If any member of the project staff has or is given such information, he or she is required to report it to authorities. The obligation to report includes alleged or probable abuse as well as known abuse.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in a federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse, but not for federal, state, or local civil, administrative, legislative, or other proceedings); if you have consented to the disclosure; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect or harm to self and others.

Individuals and organization that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information. These individuals and organizations include: the Institutional Review Board that reviewed this research; the National Institute for Child Health and Human Development; and University of Oregon auditors.

Seven years after completion of this study, all consent documents will be destroyed.

What are the risks if I participate in this research?

The risks or discomforts of participating in this research include privacy and psychological risks.

We anticipate few discomforts or risks will be involved in your family's participation in this project. In fact, in our experience, families usually very much enjoy their participation. Nevertheless, some of the questions in the questionnaires do address personal information about you and your family and might be considered an invasion of your privacy (e.g., questions about the marriage). Also, some young children may show mild frustration or distress during the home situations involving you placing demands on your child (e.g. asking them to clean up). Your child may also face some mild frustration / boredom during the lab visit during the developmental assessment due to its length (approximately 40-60 minutes). And even though we take many precautions to protect your data, there is always a possibility of a breach of confidentiality. For these mild or minor risks, a member of our staff will always be available to address your questions or concerns.

What are the benefits of participating in this research?

You may or may not benefit from participating in this research. Potential benefits to your family following the intervention include: (1) possible reduction in parental stress, (2) possible improvement in parenting behaviors, and (3) possible decline in children's behavior problems. In addition, you will receive a short summary of your child's current and previous behavioral functioning based on study assessments after completion of the 12-month follow-up visit. In addition, as part of the study you will have access to a research staff with expertise in child development who will be able to answer your questions about your child's development, need for services, and local resources.

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision to participate or withdraw from this study will have no effect on other services you may be receiving (e.g., from your Education Service District, medical provider, or from the University of Oregon) and will not affect your relationship with the researchers or the University of Oregon.

In addition, you may review all video and/or audio recordings that are made during any visit, and you have the right to request that any such tape be erased in full or in part.

If you decide to withdraw from the research study, please contact [redacted] to request that your information not be used for research.

Will it cost me money to take part in this research?

There is no cost to you for participating in this study.

Will I be paid for participating in this research?

For taking part in this research, you may be paid up to a total of $450 (paid via check at time of each assessment). Your compensation will be broken down as follows:

- $50 pre-intervention family assessment (which includes interviews, questionnaires, and family play task);
- $25 pre-intervention Covid-19 survey;
- $25 parent portion of developmental assessment of child ;
- $75 post-intervention assessment (similar to the pre-intervention assessment);
- $25 post-intervention Covid-19 survey;
- $100 6-month follow-up assessment (similar to the pre-intervention assessment);
- $125 12-month follow-up assessment (similar to the pre-intervention assessment); and
- $25 developmental assessment of child (Note: this assessment will only happen if physical distancing restrictions are lifted before the end of the study period).

If your family withdraws from the study before completion, you will not receive the remaining payments. In the event that a visit needs to be rescheduled, your family will be compensated upon completion of the rescheduled visit.

Your child's teacher will also be paid up to a total of $100 (also paid via check at time of each assessment). Your child's teacher will receive $25 each time he/she completes the questionnaire about your child:

- $25 pre-intervention assessment;
- $25 post-intervention assessment;
- $25 6-month follow-up assessment;
- $25 12-month follow-up assessment.

Please be aware that compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separately from research data. If you receive $600 or more in a calendar year, you may be contacted to provide additional information for tax reporting purposes.

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510

UNIVERSITY OF OREGON

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

I consent to participate in this study.

Name of Adult Participant	Signature of Adult Participant	Date

Information you provided during the phone screening regarding parenting stress will be used in the study.

Initial the space below if you consent to the use of this information.

___ I agree to the use of information collected during the phone screening.

As described above, your family will be audio/ video recorded during the home play tasks and your child will be recorded during the developmental evaluation at the research lab visit. These recordings will only be used for research purposes.

Initial the space below if you consent to the use of audio/ video recording as described.

___ I agree to the use of audio/video recording.

Official Title: The PRO-Parenting Study: Helping Parents Reduce Behavior Problems in Preschool Children with Developmental Delay

Brief Title: Partnerships in Research for Optimizing Parenting (PRO-Parenting Project)

NCT Number: NCT03599648

Document Type: Teacher Consent Form

Document Date: 11/12/2019

UNIVERSITY OF OREGON

Consent for Research Participation

Title:	Partnerships in Research for Optimizing Parenting (PRO-Parenting Project)
Sponsor:	National Institute of Health, NICHD
Researcher(s):	Laura Lee McIntyre, PhD, University of Oregon
	Cameron Neece, PhD, Loma Linda University
Researcher Contact Info:	541-346-5123
	llmcinty@uoregon.edu

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research is to compare two interventions aimed at increasing parental well-being and improving parenting skills in order to ultimately improve child behavior outcomes for children with developmental disability. Teachers are asked to complete a survey about a child in their class in order to help researchers gain a complete picture of the child's behavior.
- **Duration.** It is expected that your participation will last about 20 minutes. However, we will be collecting these surveys from the teacher of a participating child 4 times over an 18 month period. If the child of the participating family is still in your class during this time frame, you will be asked to complete the survey again.
- **Procedures and Activities.** You will be asked to complete a brief, 2-page questionnaire about the child.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include [privacy and psychological risks. You may feel some discomfort answering questions about the behavior of a child in your classroom. Although precautions are taken to protect the privacy of your data, there is always a risk of a confidentiality breach.
- **Benefits**. Some of the benefits that may be expected include psychological or emotional benefits, and benefits to the scientific community. You may find it interesting and rewarding to contribute to scientific research and advance knowledge about child development and well-being in families with a child with developmental disability. Knowledge gained from this study may assist in the development of more effective family intervention to improve child behavior in children with developmental disability.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Who is conducting this research?

The researchers, Dr. Laura Lee McIntyre from University of Oregon and Dr. Cameron Neece from Loma Linda University, are asking for your consent to this research.

Why is this research being done?

The purpose of the research is to compare two interventions aimed at increasing parental well-being and improving parenting skills in order to ultimately improve child behavioral outcomes. The primary intervention we

will be using is a behavioral parent training (BPT) program where parents will learn parenting strategies to enhance their relationship with their child as well as help manage their child's behavior problems. The BPT program will be supplemented with a mindfulness intervention or an educational program. We are interested in seeing how the addition of either the mindfulness or educational programs affect both immediate and longer-term outcomes for the family.

The rationale for this study is drawn from research, which suggests that parents of children with developmental delays often experience heightened parenting stress, compared to parents of typically developing children. High levels of parenting stress may affect the family over time and decrease the effectiveness of interventions. The goal of this project is to understand how to make our interventions more effective for families with children with developmental delays.

You are being asked to participate because you are the teacher of a child who has been identified as having developmental concerns and whose family is participating in this study. Teacher input is critical in terms of helping us gain a complete picture of the child. About 300 people will take part in this research.

What happens to the information collected for this research?

Information collected for this research will be used to help researchers, clinicians, and educators understand how to make interventions more effective for families with children with developmental delays.

We are likely to publish or present the results of this research. However, your name will not be used in any published reports or conference presentations about this study. We will keep your name and other identifying information confidential. Personal identifiers will be removed from data and replaced with an ID number prior to data storage and analysis.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy and the security of all your personal information, but we can never fully guarantee confidentiality of all study information. Measures we take include:

- removing all personal identifiers from data prior to storage and analysis;
- storing all original data in locked files in locked offices in our research lab; and
- coding all electronic information and storing it in a password protected file on a secure server.

All the information collected from the questionnaires will remain confidential and will be disclosed only with your permission or as required by law. Under Oregon law, the privilege of confidentiality does not extend to information about sexual or physical abuse of children or the elderly, or in the event of suicide risk. If any member of the project staff has or is given such information, he or she is required to report it to authorities. The obligation to report includes alleged or probable abuse as well as known abuse.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in a federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse, but not for federal, state, or local civil, administrative, legislative, or other proceedings); if you have consented to the disclosure; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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If you decide to withdraw from the research study, please contact [redacted] to request that your information not be used for research.

Will I be paid for participating in this research?

For completing the 2-page teacher survey, you will receive a $25 check. We may contact you again (up to 3 more times) within the next 18 months to complete another survey about the participating child. If so, you will receive $25 each time you complete the questionnaire.

Please be aware that compensation for participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separately from research data. If you receive $600 or more in a calendar year, you may be contacted to provide additional information for tax reporting purposes.

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[redacted]

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I consent to participate in this study.

Name of Adult Participant	Signature of Adult Participant	Date

Address to which my payment should be mailed: _____