

Preschooler Emotion Regulation in the Context of Maternal Borderline Personality  
Disorder

Informed Consent Document

NCT03060902

September 25, 2020



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## Consent for Research Participation

**Title:** Preschooler emotion regulation in the context of maternal borderline personality disorder

**Sponsor:** National Institute of Mental Health (NIMH)

**Researcher(s):** Maureen Zalewski, Ph.D., University of Oregon

Stephanie Stepp, Ph.D., University of Pittsburgh

**Researcher Contact Info:** (541) 346-7054

[startlab@uoregon.edu](mailto:startlab@uoregon.edu)

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You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when deciding 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.

<b>Key Information for You to Consider</b>
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- **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.** You and your child are invited to participate in a study in which researchers will be recruiting 270 mothers and their preschool children at the University of Oregon and the University of Pittsburgh. Our goal is to learn how mothers' own mental health, life experiences, and parenting styles influence the development of preschoolers' ability to regulate their own emotions and stressful experiences.

You are being asked to participate in this study because you are a mother with a preschool-aged child and because you expressed interest in our study. In order to understand how a mother's own mental health experiences influences their children, we are recruiting mothers who have a range of symptoms of a particular type of mental disorder called borderline personality disorder. In our study, some mothers will have never experienced any symptoms of borderline personality disorder, while other mothers will have experienced many symptoms of borderline personality disorder. Your participation, as well as your child's is voluntary and will not affect your relationship with the University of Oregon, any mental health or social services you are receiving, or any other organization or person.

- **Procedures and Activities.** The study includes a clinical intake that determines if you are eligible to participate in the rest of the study. If you are eligible, you will be invited to complete a series of questionnaires at 4 times during the next year as well as a final clinical interview. Also, some mothers will be invited to participate in a year-long treatment called Dialectical Behavior Therapy (DBT) Skills training.

All aspects of this study will be completed remotely. This means that we will not have face-to-face interaction with each other in the same physical space. Instead of coming to our research lab at the University, you will complete each part of the study from your home either by phone, computer, or another electronic device capable of accessing the internet. The initial clinical intake interview and the final interview will be conducted virtually using telehealth services (explained below), and you will have the option of completing the questionnaires over the phone with a member of our research staff or electronically, on your own.

Your child will also be asked to participate in an activity where he/she will be shown a group of different pictures and asked to identify which picture matches a specific word. They will be asked to complete this activity around the time that you complete the first questionnaire assessment. This task takes approximately 30 minutes. Throughout the study, you will be asked to complete questionnaires regarding your child's behavior, social skills, and other characteristics, though, your child will not need to be present for this.

The clinical intake, final clinical interview, DBT Skills training, and the 30-minute word activity with your child will all take place using the telehealth videoconference platform Zoom, which is HIPAA compliant. Videoconference can be done on any electronic device that can access the



### **Who is conducting this research?**

This study is being conducted by Maureen Zalewski, Ph.D. from the University of Oregon and Stephanie Stepp, Ph.D. from the University of Pittsburgh. Both sites will be collecting data from mother and child pairs. This study is being funded by the National Institute of Mental Health (NIMH).

The researcher Maureen Zalewski, Ph.D. is asking for your consent to this research.

### **What happens to the information collected for this research?**

The video recorded clinical intake and final interviews may be viewed to assess the quality of the interviewer and how accurately the interviewer is in rating the information you share. DBT Skills training sessions will also be viewed to assess the quality of the DBT group leaders. We will select a small sample of the intake and final interviews, and DBT group sessions (10-15%) to formally assess the interviewer or the quality of DBT being provided by the DBT group leaders to ensure high-quality diagnostic interviews and DBT. Videos of the DBT Skills groups will go to the University of Pittsburgh, a therapist at the University of Oregon, or another qualified clinician who can rate the interviews or sessions for quality assurance. You will be reminded of this should you receive DBT Skills. In addition, researchers may also view the DBT Skills group videos to code for certain behaviors. In this event, random research codes, not your name, will be used. Videos will be coded for group interactions or certain individual behaviors that cannot be connected to any one individual. In the unlikely scenario these research members recognize any individuals on the recording or a name used in the conversation, they are required to immediately turn off the recording and are not permitted to view it. All other data, including questionnaire data, will be stored and viewed with a randomized number that researchers will share and use for data analysis purposes. Your name and other identifying information will not be stored with the rest of your data.

We will study the data for the whole group and not for any one individual. We may share the results in psychological and educational presentations, books, and articles. We will never identify you by name. The video recordings, questionnaire answers, and clinical data will be destroyed 3 years after the data has been published. A de-identified data file, that will only include your unique ID and scored data, as well as your child's unique ID and scored data, will be stored indefinitely. Should you choose to have your data, as well as your child's data, submitted to an archive (explained below), your de-identified data will be stored there indefinitely. In the future, we may seek additional approval to continue this study for longer than the initial 5 years. If approved, your data may also be stored indefinitely for that purpose and we may contact you about future participation.

### **How will my privacy and data confidentiality be protected?**

Because your honest answers are so valuable to us, we will do everything we can to keep everything about you and the information you share about your child confidential (e.g., completely private). Here is how we will protect your privacy:

1. Your data will be stored such that no person who is not part of the research team will have access to your data.
2. We train all members of the research team to protect your privacy.
3. All video recorded interactions are recorded using a HIPAA compliant videoconferencing platform (Zoom). Video recordings are initially stored on safe and secure servers of the University of Oregon and later transferred to secure, online cloud storage with extra security features to encrypt and protect the data. We also label the video recordings with a random code number and not your name or other identifying information.
4. In all cases, your name and your child's name will not be stored directly with your research or treatment data. All such types of data we collect on you will be assigned a random code number. This code number will be used instead of your names. There will be one digital database, which stores your family code number(s), referral source, yours and your child's names, your birthdates, address, phone number(s),



your emergency contact information, your group assignment, and your dates of participation for the clinical intake, the 4 questionnaire assessments, and the final interview.

5. While only the research team has access to your files, you will be asked to 'opt-in' to the NIMH's National Data Archive (NDA) in which you would be asked to share your de-identified data from this intake as well as all other portions of this study (archive described below). For the NIMH's National Data Archive (NDA) reporting purposes (described below) we also generate an excel report from the digital database which lists family code numbers, mother/child names at birth, mother/child birth dates, mother/child ethnicities, mother's group assignment, and dates of participation for the clinical intake, each of the 4 questionnaire assessments, and the final interview for those who have consented to sharing their information with NDA. All digital files are password protected and stored on a secure university server and/or secure cloud storage only accessible by a limited number of key staff members.
6. No other data will be stored in the highly confidential digital database or NDA reporting excel file generated from the digital database. All such data will be stored separately, according to our approved research procedures.
7. You may also have given permission during your phone screening to communicate via text message and/or email. Text messages will only be sent and viewed using a password protected device, only accessible by the research team. Messages sent will not include your identifying information beyond your phone number unless first volunteered by you, such as the use of your or your child's names. Your names will not be saved in a contact list connected to the text account. Your phone number will be used to search for the message thread. All messages will be permanently deleted from the device upon fulfillment of the intended purpose. We use a servicer called AppToto to send automatic text reminders for appointments and therefore your phone number will transmit through their server for this purpose only. Emails will also only be sent and viewed using a password protected device, only accessible by the research team, from a University of Oregon email account.
8. We will not write/type identifying information on any document that contains your random code number that we use in working with you or your child with exception to child abuse report forms (if applicable) and/or suicide assessments (if applicable), and we ask that you do not type your name on any of the documents you fill out that contain your random code number. There are two exceptions to this. We include your name and random code on alternate contact forms and teacher report forms. Other forms that you will be asked to sign (that do not list your random code number) include consent forms.
9. We will write papers and make presentations using the information from this project for scientific purposes only, and we will never use names that could identify anyone in the study.
10. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others. This does not include the possibility that the study funder (NIMH), or the University of Oregon Institutional Review Board (UO-IRB) could audit the records for the purpose of ensuring study quality. In the case of this event the NIMH and/or UO-IRB may have access to view identifiable data for the purpose of the audit and assuring our study is following best research practices.



### **What are the risks if I participate in this research?**

Being asked questions about your emotions and experiences can sometimes be distressing and it is possible you may experience intense emotions during the clinical intake, final interview, or when completing questionnaires during the study. Furthermore, participation in treatment can also bring about intense feelings.

Another risk may be that the information you provide us would not be kept confidential, (i.e., that others would hear about it or view it without our knowledge). Although we make every effort to protect you and your child's privacy there is always a potential for a breach of confidentiality. Safeguards to protecting against a breach of confidentiality were previously described in the section of this consent form entitled, "How will privacy and data confidentiality be protected?"

The risks to confidentiality pertaining to remote (i.e., videoconference and electronic data collection) are like those of in-person participation. There are some additional risks for confidentiality when telehealth services are used, however. First, there is no way to guarantee that the telehealth software is completely secure. As with any technology, there is a chance of a security breach that would affect the privacy of personal and/or mental health information. Second, since participants will be completing sessions in their own homes, we cannot guarantee the same level of privacy we could provide in our lab or clinic. This means that you are responsible for making sure that you are in a private area where disruptions (e.g., others coming into the room or hearing what you say in another room) are minimized as much as possible.

*In order to reduce risks to confidentiality, we suggest that all video or telephone sessions occur in a private room within one's home, with no one else present, and that you wear headphones to limit the possibility of other people overhearing confidential information.*

Safeguards to protecting against a breach of confidentiality were previously described in the section of this consent form entitled, "How will privacy and data confidentiality be protected?"

### **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 whether or not to participate will not affect your relationship with the researchers or the University of Oregon.

### **Will I be paid for participating in this research?**

Yes. To compensate you for your time, mothers receive a total of \$260 for participation in the entire study. Payment breakdowns are as follows:

1. \$40 for the clinical intake; \$40 for questionnaire assessment 1, \$50 for questionnaire assessment 2, \$60 for questionnaire assessment 3, \$30 for questionnaire assessment 4, and \$40 for the final interview.
2. Mothers in DBT Skills training will receive the treatment at no cost.
3. Teachers or caregivers completing the alternate caregiver questionnaire will also be compensated for their time. They can receive a total of \$80, \$20 for each questionnaire completed.



Please note, 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 separate from research data. If you receive \$600 or more in a calendar year, you may be contacted to provide additional information (e.g., Social Security Number) 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:

Maureen Zalewski, Ph.D.

(541) 346-7054

startlab@uoregon.edu

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

**STATEMENT OF CONSENT**

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to decide 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.

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Name of Adult Participant

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Signature of Adult Participant

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Date

**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.

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Name of Research Team Member

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Signature of Research Team Member

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Date



### **National Data Archive**

Data from this study may be submitted to the NDA. NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed.

Deidentified information means that all personal information about research participants such as name, address, phone number is removed and replaced with a code number.

With an easier way to share, researchers hope to learn new and important things about mental health more quickly than before.

During and after the study, the researchers will send deidentified information about you and your child's health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to you and your child's deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to you and your child's privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental health problems so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available online at <http://data-archive.nimh.gov>.

Please initial the line below if you would like to **opt-in** to sharing you and your child's data with the NDA and complete the information on the next page.

Yes, I would like to share mine and my child's data with the NDA: \_\_\_\_\_  
Participants Initials

### **To participate in this database, we need to provide the following information to the NDA:**

Your Name at Birth: \_\_\_\_\_  
First Middle Last

Your Date of Birth: \_\_\_\_\_

Your City of Birth: \_\_\_\_\_

Child's Name at Birth: \_\_\_\_\_  
First Middle Last

Child's Date of Birth: \_\_\_\_\_

Child's City of Birth: \_\_\_\_\_

*At the end of this intake, you may be eligible to participate in other related studies. If so, a researcher will contact you to explain the study and obtain your informed consent. You can decide to participate or not without it affecting*





*your participation in this study.*

**If you prefer not to be contacted about other research studies, please initial:** \_\_\_\_\_