UNIVERSITY of ROCHESTER

Permission Form

Parent Emotion Socialization and Child Emotion Regulation in FASD
Principal Investigator: Christie L. M. Petrenko, Ph.D.

This permission form describes a research study, what you may expect if you decide to allow your child or the child in your custody to take part, and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to allow the child to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If your child joins this study, you can change your mind and stop at any time.
- If you choose not to take part, your child's routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to your child.

Introduction:

Your child or the child in your custody is being asked to take part in this study because he or she is a child between the ages of 4 and 12 with a history of prenatal alcohol exposure.

This study is being conducted by Christie Petrenko, Ph.D. at the Mt. Hope Family Center, University of Rochester.

Purpose(s) of Study:

The purpose of this study is to learn about the emotion regulation skills of children with fetal alcohol spectrum disorders (FASD) and different strategies that may improve these skills. This study is also testing whether a training program taught to caregivers is helpful.

Description of Study Procedures:

If you give permission for your child or child in your custody to participate, the following will happen:

Research Visits

- The child will participate in several research visits at Mt. Hope Family Center with a caregiver. These visits will happen on the following schedule:

187 Edinburgh Street · Rochester, NY 14608
585.275.2991 · 585.454.2972 *fax*

RSRB Approval Date: 9/18/2020
Expiration Date: 9/17/2021

When?	Who Participates?	How Long?
Study start	Caregiver and child	2-2.5 hours
3 months	Caregiver and child	2-2.5 hours
6 months	Caregiver and child	Caregiver: 1-1.25 hours Child: 25 minutes

- Additional visits may be scheduled if we are not able to complete the measures in one session.
- **Child research visit activities**. Your child will be asked to:
    - Complete a brief measure of verbal and nonverbal problem-solving skills.
    - Play several games on an ipad.
    - Have their heart rate measured while completing a task that is designed to be mildly disappointing. Two ECG pads are placed on the chest with a small recorder.
    - Talk about what it is like when they feel happy, sad, and mad.
    - Complete a questionnaire about depression symptoms, including a question about hurting themselves.
    - Play or relax with study staff while the caregiver is finishing activities.
- **Caregiver research visit activities**. The caregiver will be asked to complete interviews and questionnaires about:
    - The child's background, including any past stressful experiences.
    - The child's behavior and how s/he handles emotions.
    - The caregiver's views on his/her emotions and your child's emotions.
    - The caregiver's relationship with your child.
    - Stress the caregiver may experience.
    - What they thought about the Tuning Into Kids Program.
- **Research visit activities including both child and caregiver**.
    - We will ask your child and the caregiver to have a conversation about several recent experiences involving different emotions.
- Visits will be audio and/or video taped to help us record what was said by your child and the caregiver.
- We will not share the results of these visits with you or tell you about your child's answers. However, if we are concerned about the welfare of the child we will inform you about our concerns, and if needed, assist with finding help.
- We will review your child's electronic medical records from previous FASD evaluations. If your child was seen by an outside provider, we will ask you to sign a separate release form for us to access those records. We will ask your verbal permission to review these records prior to your first research visit and signing this consent form.

<u>Tuning Into Kids (TIK) Program</u>

After the first research visit, half of families will be randomly selected to participate in the Tuning Into Kids program right away. The other half of families will receive the TIK program about 6 months later after completing the other two research visits. Being in this project does not prevent your child from continuing or seeking other services.

The caregiver involved in the study will participate in the Tuning Into Kids Program. This program involves:

- Meeting in a small group with other caregivers raising children with FASD.
- 8-week program that meets weekly for 2 hours at Mt. Hope Family Center or other community location.
- Learn and practice an approach of responding to children's emotions and behavior.

Number of Subjects:
A total of 120 families of children with FASD will participate in this study.

Duration of the study:
Your child's participation in the study will last approximately 6 months.

Risks of Participation:
Some children may find that answering questions or completing tasks is stressful or boring at times. Staff are trained to be sensitive to children's needs and offer them any support they need. Your child is always free to skip any questions s/he is not comfortable answering and to take a break if needed. Some children may also find the heart rate recorder uncomfortable. Your child can stop this task or try again later if needed.

If you choose to email the study team, you should consider the following risks. These include, but are not limited to, the following:

a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
b) E-mail senders can easily misaddress an e-mail.
c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
f) E-mail can be used to introduce viruses into computer systems.

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 your child. At most, the Web site will include a summary of the results. You can search this website at any time.

Benefits of Participation:
Your child may or may not benefit from the caregiver participating in the Tuning In to Kids program.

Sponsor Support:
The University of Rochester is receiving funds from the National Institute on Alcohol Abuse and Alcoholism to conduct this study.

Payments:
Your child will each receive payment (cash or toy equivalent) for participation according to the following schedule:

When?	Caregiver Payment	Child payment
Study start	$50	$20

3 months	$50	$20
6 months	$25	Small toy from prize box

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information related to your child private. In order to do so, we will treat your child's information in strict confidence to the extent provided by law. Your child's identity will be coded and will not be associated with published results. Your child's code numbers and any identifying information will be kept in locked files or secure encrypted servers that only the Principal Investigators or study staff can access. Study staff respect your family's desire for privacy. If, however, concerns arise about your child's welfare or that of someone else in your family, a study staff member will talk with you about these concerns to make sure that any support you need is made available. Study staff may need to share information with outside authorities in the event that a study subject reports a danger to themselves or others. As professionals, study staff are required to report suspected child or elder abuse. If this occurs, they will make every effort to talk with you prior to filing a report.

Sometimes researchers also need to share information that may identify your child with people that work for the University, regulators, or the study sponsor. If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study staff will collect your child's personal information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your child's study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates and external providers for whom you provide us a release.

Who may use and give out information about your child?

- Study staff

Your child's information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- National Institute of Alcoholism and Alcohol Abuse
- University of North Carolina, which will analyze heart rate data and prosody from speech sample

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies your child will not be used.

What if I decide not to give permission to use and give out my child's health information?
Then your child will not be able to be in this research study.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your child's health information at any time. You do this by sending written notice to study staff. Upon receiving the written notice, the study team will no longer use or disclose your child's health information and your child will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw my child from the study?
Yes. If you withdraw your permission for the child to be in the study, no new health information identifying your child will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my child's health information protected after it has been given to others?
No. There is a risk that your child's information will be given to others without your permission.

Certificate of Confidentiality
To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

Conditions for the Use of E-mail:

The researcher cannot guarantee but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. You and the researcher must consent to the following conditions:

a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
c) E-mail communications between you and the researcher will be filed in the research record.
d) Your messages may also be delegated to any member of the study team for response.
e) The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
f) You should not use e-mail for communication regarding sensitive medical information.
g) It is your responsibility to follow up and/or schedule an appointment if warranted.

E-Mail Instructions

a) Avoid use of your employer's computer.
b) Put your name in the body of the e-mail.
c) Put the topic (e.g., study question) in the subject line.
d) Inform the researcher of changes in your e-mail address.
e) Take precautions to preserve the confidentiality of e-mail.
f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

Contact Persons

For more information concerning this research or if you feel that your child's participation has resulted in any emotional or physical discomfort please contact: **Christie Petrenko, Ph.D.,** Mt. Hope Family Center, University of Rochester, 187 Edinburgh Street, Rochester, NY 14608, **Telephone:** 585-275-2991.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your child's rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to allow your child or child in your custody to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which the child is entitled. In the event that you do withdraw the child from this study, the information you or the child have already provided will be kept in a confidential manner.

Signature/Dates

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to your child;
- Other options your child may have instead of being in the study;
- How your child's personal information will be protected;
- What to do if you have problems or questions about this study.

Permission

I have read (or have had read to me) the contents of this permission form and have been encouraged to ask questions. I have received answers to my questions. I give my permission for my child or child in my custody to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Parent/Guardian: _____ Print Name

Child's Name: _____ Print Name of Child

Parent/Guardian: _____ Signature

_____Date

ASSENT of Child: CHECK ONE - REQUIRED

☐ Child is 4-7 yrs. old - Assent is not required.
☐ Child is 8-12 yrs. old - Use separate Assent Document.

Person Obtaining Permission

I have verbally presented the permission to the parent or guardian and/or the parent or guardian has read this form. I will provide the parent or guardian with a signed copy of this form. An explanation of the research has been given and questions from the parent or guardian were solicited and answered to their satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate time to read the permission form before signing.

_____ Print Name and Title

_____ Signature _____Date