UNIVERSITY of ROCHESTER

Consent/Parent Permission Form

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

This consent form describes a research study, what you may expect if you and your child decide 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 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 you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction:

You are being asked to take part and give permission for your child to participate in this study because you are a parent, foster parent, or legal guardian of 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 agree to take part in the study and give permission for your child participate, the following will happen:

Research Visits

- You and your child will participate in several research visits at Mt. Hope Family Center. 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 if you are finishing caregiver activities.
- **Caregiver research visit activities**. You will be asked to complete interviews and questionnaires about:
    - Your child's background, including any past stressful experiences.
    - Your child's behavior and how s/he handles emotions.
    - Your views on your and your child's emotions.
    - Your relationship with your child.
    - Stress you may experience as a parent.
    - What you thought about the Tuning Into Kids Program after completing it.
- **Research visit activities including both child and caregiver**.
    - We will ask you and your child to have a conversation about several recent experiences in your family involving different emotions.
- Visits will be audio and/or video taped to help us record what was said by you or your child.
- 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 your child we will inform you about our concerns, and if needed, assist you 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 you or your child from continuing or seeking other services.

The Tuning Into Kids 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 participation in the study will last approximately 6 months.

Risks of Participation:
Some children and caregivers may find that answering questions or completing tasks is stressful or boring at times. Staff are trained to be sensitive to caregivers' and children's needs and offer them any support they need. You and your child are always free to skip any questions you are 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.

You could also experience discomfort talking about emotions or sharing experiences with other caregivers in TIK groups. Staff are trained to create a warm and supportive environment and offer support as needed. You are always free to not participate or take a break if you are uncomfortable. It is also possible that other caregivers could tell information you shared about your family in the group to people outside of the study. Staff will set group rules to discourage this and will provide real life examples of what is ok and not ok to discuss with people outside the group.

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

Benefits of Participation:
It is possible, although not guaranteed, that you and your child may benefit from your participation in the Tuning Into Kids intervention.

Sponsor Support:

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

Costs:
There will be no cost to you to participate in this study.

Payments:
To compensate you for your time, you and 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 collected from you private. In order to do so, we will treat your information in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with published results. Your 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 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 you 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 personal information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your 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 you?

- Study staff

Your 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 samples

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 you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you 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 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 health information and you 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 from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your 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 your 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 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 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 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 you are entitled. In the event that you do withdraw from this study, the information you 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 you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Parental Consent and Permission

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

Foster/Parent/Guardian: _____ Print Name

Child's Name: _____ Print Name of Child

Foster/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 Consent

I have verbally presented the consent to the parent, foster parent, or guardian and/or the parent, foster parent, or guardian has read this form. I will provide the parent, foster parent, or guardian with a signed copy of this form. An explanation of the research has been given and questions from the parent, foster 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 consent form before signing.

_____ Print Name and Title

_____ Signature _____Date