The Children's Hospital of Philadelphia®

## Informed Consent Form for Study Participation

**Study Title:** **A Pilot Study to Identify Best Practices for Implementation of a Positive Parenting Training Program in the Foster Care Population**

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**Principal Investigator:** Joanne N. Wood Telephone: (267)-426-3107

**Study Overview:**

You are being asked to take part in this research study because you are a foster caregiver of a foster child, who is between 18 months and 6 years old.

The purpose of this research study is to learn how to best implement a brief parenting program called Child Adult Relationship Enhancement in Pediatric Primary Care (PriCARE) for foster caregivers and to determine how this program impacts parenting.

If you agree to take part, your participation may be up to approximately 12 months and will include participating in the PriCARE program and completing two study interviews via virtual videoconference, phone, or email, which will each last 1-2 hours.

The main risks of this study are increased stress from the interview questions.

You will not benefit directly from participating in this study. However, you may receive a Certificate of Completion of this training.

Participation in the study is voluntary. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

If you are interested in learning more about the study, I will continue to read the consent form to you. If there is anything that you do not understand as I tell you more about the study, please ask questions. The form I am reading to you gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. In the sections that follow, the word "we" means the study doctor and other research staff.

### How many people will take part?

About 60 foster caregivers will take part in this study.

### What is involved in the study?

The PriCARE program lasts about 6 weeks and will involve multiple visits virtually for the training. In addition to the PriCARE program, the main study involves two interviews that will occur via telephone, videoconference, or e-mail.

**How long will you be in this study?**

If you agree to take part, your participation may be up to approximately 12 months and will include the PriCARE program and will involve two study interviews.

## What are the study procedures?

The study involves the following procedures.

Interviews: A team member will ask you a number of questions via the phone, email, or through a HIPAA-compliant videoconference platform, including questions about your background and home life, as well as questions about your parenting practices. Some, but not all, of these questions will be repeated throughout the study. Also, throughout the study, you will be asked to report if you think that anything bad has happened as a result of the study.

Qualitative interviews will be recorded, but only audio files will be kept and stored. Your answers and information will also transcribed by a CHOP-approved vendor. No one other than the research team and the transcription service will hear the recordings. If someone's name is mentioned, it will not be included in the transcription.

PriCARE Program: Child Adult Relationship Enhancement in Pediatric Primary Care (PriCARE) is a group parent training program. The goals of the program are to teach you skills that help improve your child's behaviors.

- Each PriCARE session will be held virtually and led by 1-2 PriCARE facilitators.
- The total curriculum is approximately 9 hours divided into shorter sessions (approximately 6 weeks, 80 minutes a week).
- Approximately 4 to 13 parents will attend each session.
- Children do not attend the group sessions.
- You are encouraged to practice the skills you learn at PriCARE between the sessions.
- Text messages will be sent to you such as facts, tips, reminders/encouragement.

**Study Interview Schedule**
The table below provides a brief description of the purpose and duration of each study interview.

| Interview | Purpose | Main Procedures | Duration |
|---|---|---|---|
| Interview 1 | Baseline | Baseline questions, measure parenting style | 1-2 hours |
| Interview 2 | Follow-up | Measure parenting style and learn about your perspectives on and satisfaction with the PriCARE intervention | 1-2 hours |

**What will be done with my data during this study?**

During the study, we will collect your data via interviews.

## What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

While in this study, you are at risk for the following:

**Risks associated with PriCARE training and interview questions:**

It is possible that the training or questions in the interview will cause you increased stress. You can choose to not answer any question that makes you feel uncomfortable. You can also choose to not complete the interview. Based on your answers to some of the questions, you may be offered mental health resources.

**Risks associated with text messaging:**

You may incur charges based on the text messages that you receive and / or send.

**Risk of PriCARE and Group Participation**

You might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable in response to the potentially sensitive focus group questions..

As with any study involving collection of data, there is the possibility your confidentiality information will be shared with others. Every precaution will be taken to protect your personal information. Identifiable information collected about you will be stored on a secure password-protected server and within a password-protected database. A study identification number will be used on all data forms instead of names and other private information.

The interviewer and session trainers are mandated reporters, which means he/she is required by law to report any reasonable suspicion of child abuse or neglect to the appropriate authorities, such as child protective services or the police. If you provide information about a child being abused or neglected and the team member needs to make a report, they will tell you. In addition, any information you provide about intent to harm yourself or others will be reported to authorities, as required by law.

Overall, the risks to caregivers of psychological distress and child protective services involvement are no greater than that associated with routine clinical care.

**Risks Associated with Audio Recording**

The main risk to you is that someone could find out you were in this study. But we will do our best to keep your information confidential, so we think this risk is very low. Some people may feel uncomfortable having the interview recorded. You may skip any question or stop the interview at any time.

**Risks associated with Video Recording**

There is the possibility, that your video might be seen by someone outside of the study team. To prevent this, only audio data will be downloaded onto CHOP-issued devices. Videos are only collected due to how online platforms record audio.

Overall, the risks to caregivers of psychological distress and child protective services involvement are no greater than that associated with routine clinical care.

Risks associated with loss of privacy

There is the possibility that your confidential information will be disclosed to people outside the research team. Every precaution will be taken to protect you and your child's personal information. Identifiable information collected about you will be stored on a secure password-protected server and within a password-protected database. A study identification number will be used on all data forms instead of names and other private information. Audio recordings of each interview will be uploaded to ADA transcription website for professional transcription. All audio files uploaded to the ADA website will be encrypted to protect the data. Names and identifiers used during the interview will be removed.

If you provide information that your child (or any child) is being abused or neglected, the interviewer is a mandated reporter, which means he/she is required by law to report any reasonable suspicion of child abuse or neglect to the appropriate authorities, such as child protective services or the police. You will be informed by the interviewer if he/she needs to make a report of child abuse or neglect. In addition, any information you provide about intent to harm yourself of others will be reported to authorities, as required by law.

## Are there any benefits to taking part in this study?

No direct benefit can be guaranteed to you from taking part in this study. You might experience decreased behavioral problems with your child. The knowledge gained from this research study may benefit future children with behavior problems and their foster caregivers. You may receive a Certificate of Completion of this training.

## Do you need to give your consent in order to participate?

If you decide to participate in this study, you must tell us that you agree. A copy of the study consent will be given to you to keep as a record.

**What are your responsibilities?**

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

**What happens if you decide not to take part in this study?**

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later, there will be no penalties or loss of any benefits to which you are otherwise entitled.

**Can you stop your participation in the study early?**

You can stop being in the study at any time by speaking with the study doctor, Dr. Wood (267-426-3107). You do not have to give a reason.

## What about privacy and confidentiality?

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. People from oversight agencies and organizations such as the Department of Health and Human Services and the Office for Human Research Protections may also look at your study records.

ADA Transcription Services, who will be transcribing the audio recordings, will have access to both the questions asked during qualitative interviews and your answers, but will de-identify the transcriptions.

The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation about the study.

By law, CHOP is required to protect your private information. The investigator and staff involved in the study will keep your private information collected for the study strictly confidential.

## Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

**Will there be any additional costs?**

You will not be responsible for any costs of this study. The Ray E. Helfer Society is providing financial support and material for this study.

**Will you be paid for taking part in this study?**

- You will be paid $40 via an Amazon gift card for each completed interview, for up to $80 total.
- For virtual groups
    - To encourage on-time attendance to groups, each participant that arrives within the first five minutes of the group start time will receive a $10 Amazon gift card. You can earn up to $60 total, for attending all 6 PriCARE sessions.
    - A toy will be sent to you and your child for PriCARE skill practice.

**Who is funding this research study?**

The Ray E. Helfer Society is funding this research.

## What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Wood at 267-426-3107. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

## What will be done with my data when this study is over?

Your data will not be used for any future research after this study is complete.

**Documentation of Verbal Consent to Take Part in this Research Study *(Subjects who take part by phone)***

Name of Subject (Foster Caregiver)

The research study and consent form was explained to:

Person Providing Consent

The person who provided consent confirmed that all of their questions had been answered and they agreed to their (foster caregiver) participation in this research study.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date