

Cover Page
Informed Consent Form

Official title of the study: Intervention to Improve Outcomes for Foster Children Reunited with Their Birth Families

Brief title: Families Together: Intervention for Reunified Families

NCT Number: NCT04382677

Study consent forms:

Parent Consent Form

Parent HIPAA Form

Social Worker/DCYF Consent Form

Social Worker/DCYF HIPAA Form

Date of documents: 6/16/2021 (date of IRB approval)



Families Together
**UNIVERSITY of
WASHINGTON**
*Child, Family, & Population
Health Nursing*



FAMILIES TOGETHER PARENT CONSENT FORM

Researchers

University of Washington

Child, Family, & Population Health Nursing:

Monica Oxford, Ph.D.
Lead Researcher
206-685-6107/877-705-2759
mloxford@uw.edu

Mary Jane Lohr, M.S.
Project Director
206-616-3373
mjlohr@uw.edu

Susan Spieker, Ph.D.
Investigator
206-543-8453
spieker@uw.edu

Kristin Klansnic, M.S.W.
Recruitment Coordinator
206-519-7330
klansnic@uw.edu

Researcher's Statement

Why is the research taking place?

- We are asking you and your child to be in a study. The study will compare 2 programs for families. We want to know which program is most helpful for families.
- We are asking you and your child to be in it because: (1) You recently were reunited with a child who was placed in foster care. (2) You have a child 1-5 years old who was in foster care. (3) You are receiving services from the Department of Children, Youth, and Families (DCYF) and live in the study area. We hope to enroll 255 families into the study.
- The National Institute of Child Health and Human Development funds this study.

What will I be asked to do?

- If you agree to be in this study you will get 1 of 2 services designed to help families with young children:
 1. *"Promoting First Relationships®" (PFR)* is a 12-week home visit service with a parenting support specialist. Each visit would be at a time that is good for you and your child. Each visit lasts about 1 hour. The specialist will talk with you about your child's healthy social and emotional growth. The visits will include time for you and your child to play together.

Five of the play visits would be videotaped. The specialist will watch the tapes with you and give you positive feedback. The sessions will also focus on deeper feelings and needs that lead to behavior problems in children. Sometimes the visit might be videotaped so we can make sure the specialist is doing what she is supposed to do.

2. *“Resource & Referral”* is a service over the phone. You would talk with a trained professional about your family’s needs. You would get referrals to help you meet those needs. You would be mailed a Local Services Resource Packet about services in your area. You would receive follow-up phone calls once a month for 3 months, to check in with you and see if you would like more information. You would be able to contact the specialist at any time if you had any concerns or wanted more referrals.

- You will be put into 1 of the 2 groups (Promoting First Relationships® or Resource & Referral). You have a 50/50 chance (like a coin toss) of being in either group. After your first visit we will tell you which group you are in.
- There will be 3 research visits with you and your child. The first visit would be after you agree to participate. The second will be about 4-5 months later, when you finish working with the specialist. The third visit will be about 6 months later. These visits are to collect information for research. They are not part of the services you get with your specialist. The visits include interviews, activities, and play time between you and your child. Parts of the visits will be videotaped and audio taped. The research visitors have passed criminal background checks.

Research Home Visits (2 hours)

Free play: You and your child will play with a set of toys. You will be asked to play as you usually do.

Teaching activity: You will choose an activity from a list that your child hasn’t done yet. We will ask you to teach your child how to do it. It doesn’t matter if your child actually does it.

Video viewing: You will watch a part of your free play and teaching activity videos with the research visitor. She will ask you questions about the video.

Parent interview: You will be asked about topics including your child’s behavior, your ideas about parenting, your recent mood, current and past stressful events, and background information.

Here are examples of the most sensitive things you will be asked about.

Does your child get in many fights?

Does your child destroy things?

Have you been feeling down, depressed, or hopeless?

Have you ever been sexually abused?

If you have any questions or concerns about any of the activities, we are happy to discuss them with you. You are free not to answer any questions.

- We will ask you to sign a form giving us permission to get information in your CPS in DSHS Department of Children, Youth, and Families (FAMLINK). We will collect CPS and child welfare information up to 5 years after you finish your study services.
- Promoting First Relationships® and Resource & Referral services are provided by trained professionals. The parenting support specialists who do the PFR sessions are social workers and counselors who work for local agencies (Navos, ChildStrive, Answers Counseling) and the University of Washington. The Resource & Referral specialists and research visitors work for the University of Washington.
- Research visits will be in your home at a time that is good for you and your child. If you are in the Promoting First Relationships® program, the 12 weekly sessions will be in your home. If you are in the Resource & Referral program, the 3 sessions will be done on the phone.
- The study lasts about 12 months.

What are the possible risks or harms if I take part?

- You may feel that the questions we ask are an invasion of privacy. You may feel uncomfortable being videotaped. You may feel uncomfortable answering questions about yourself and your child. You may be uncomfortable releasing information about reports to CPS and your work with DCYF. These are common and normal feelings. The visit may be inconvenient. To help you feel more comfortable, you and your child may take a break at any time. You can refuse to do any study activity. You may end or postpone a session at any time.
- There is a small risk to your privacy. We will do everything we can to protect your privacy. Only the research team will see study information and videotapes. Your tapes and papers will be kept in a locked University office. Only the research staff uses this office.
- If anything happens in the study that upsets you, we want you to contact one of the researchers. They are listed on the first page of this form.

What are the possible benefits?

- You will receive free services that may help you and your family.
- What we learn from the study may help families in the future. It may help us improve programs for families reunited with children who have been in foster care.



What are my choices if I *don't* take part?

- The study is voluntary. You don't have to participate. You can withdraw from the study at any time. You would not lose any other services or benefits.
- You do not have to sign this form to get services from DSHS or any other agency. But you can only get the study's support services if you decide to be in this study.
- If you leave the study, we will still keep all information we collected from you. But we won't contact you again.

Who would see study information about me?

- Only members of the research team will look at your tapes and study forms. All materials will be kept in a locked file in our office at the University of Washington. A code number will be used on all study information. Your name won't be on your study information. Your contact information will be kept in a locked file cabinet. Computer files will only include your code number. We will destroy names, phone numbers, and research tapes by April 30, 2030, 6 years after the end of the study.
- The researchers won't give information about you and your child to anyone else. We will only use your information for this study.

Would I be paid for my time? Will the study cost me anything?

- You will get \$75 in cash for each research visit. You would get a total of \$225 if you do all of the research visits.
- The study won't cost you anything. Services are free. The study pays for services and materials you will get.

What else do I need to know?

- If your child is removed from your home during the study: (1) You won't be eligible to get any more study services, and (2) You won't be eligible to take part in the research visits.
- We have permission from the Department of Children, Youth, and Families for your child to participate in the study.



- We want to protect your privacy. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers will 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. 1) If we suspect that a child is being abused or neglected, we will report it to CPS. 2) If you are thinking about harming yourself or other people, we will call the Crisis Line, or the local police if there is immediate danger.
- If you have questions about the study, you may call Families Together. Dr. Oxford is the lead researcher. She can be reached at 206-685-6107 or toll free at 877-705-2759.
- You may call the Washington State Institutional Review Board if you have questions about your rights or concerns/complaints about the research. The WSIRB oversees this study to make sure that the rights of people who take part are protected. You can call at 1-800-583-8488. You don't have to give your name if you call.

INVESTIGATOR SIGNATURE	DATE
If you agree to participate: The study described above has been explained to me. By signing below, I voluntarily consent for me and my child to take part in this research. I have been told that I can refuse to answer any question or leave the study at any time, without penalty. I have had a chance to ask questions. I have been told that I may call the researchers if I have any questions about the research. I have been told that I may call the Washington State Institutional Review Board if I have questions about my rights or if I have concerns or complaints about the study.	
PARTICIPANT SIGNATURE	DATE
PARENT'S PRINTED NAME	
CHILD'S PRINTED NAME	

Copies to: Participant
Investigator's File



Families Together

Dr. Monica L. Oxford, Principal Investigator
206-685-6107 / 877-705-2759

Authorization for Use and Disclosure of Protected Health Information

I, _____, give permission for DSHS/DCYF to give
(Study participant name)

protected health information in my Child Welfare (CPS) records to Dr. Oxford, or to a member of her research team.

This authorization allows DSHS/Department of Children, Youth, and Families (DCYF) to disclose information about contacts with Child Protective Services (CPS), including dates of any reports, what the report was about, and what happened after the report. DSHS may release my records from my child's birthdate through 5 years after we finish getting services from the Families Together program.

My protected health information will only be used for the study called Families Together. The researchers won't use it for any other reason. The researchers will keep my health information confidential. They won't give it to anyone who isn't connected to this study.

I'm not required to sign this form to get services. DSHS/DCYF will only give my protected health information to the researchers if I sign this form. I may cancel this authorization at any time by writing to DSHS/DCYF. If I cancel this authorization, the researchers will keep the information they already have.

My privacy rights are described in detail in the DSHS Notice of Privacy Practices for Client Medical Information (available at <http://dshs.wa.gov>).

This authorization expires April 30, 2030 unless I cancel it before then.

PRINT STUDY PARTICIPANT NAME

Study Participant Signature

Date

cc: Study Participant, DSHS/Department of Children, Youth, and Families, Researcher



Families Together
**UNIVERSITY of
WASHINGTON**
*Child, Family, & Population
Health Nursing*



FAMILIES TOGETHER SOCIAL WORKER/DCYF CONSENT FORM

Researchers

University of Washington

Child, Family, & Population Health Nursing:

Monica Oxford, Ph.D.
Lead Researcher
206-685-6107/877-705-2759
mloxford@uw.edu

Mary Jane Lohr, M.S.
Project Director
206-616-3373
mjlohr@uw.edu

Susan Spieker, Ph.D.
Investigator
206-543-8453
spieker@uw.edu

Kristin Klansnic, M.S.W.
Recruitment Coordinator
206-519-7330
klansnic@uw.edu

Researcher's Statement

Why is the research taking place?

- We are asking you to give permission for a dependent child on your caseload, _____, to be in a research study. The purpose of this research study is to compare the effectiveness of two programs which aim to support families.
- We are asking for your permission because: (1) The child was recently reunited with his/her birth family, after spending time in foster care. (2) The family is receiving services from DCYF and lives in the study area. (3) The child's birth parent is interested in participating in the study with the child. (4). You are this child's caseworker. We hope to enroll 255 families into the study.
- The research is funded by the National Institute of Child Health and Human Development. It is being conducted by the University of Washington in partnership with the Department of Children, Youth, and Families.

What will I be asked to do?

You are being asked to give permission for the child to participate in the study with his/her birth parent. You are asked permission for the child to participate and for the birth parent to reveal private information about the child. We are enrolling birth parent/child pairs.

We are also asking your permission for the researchers to collect information in the child's record kept by DCYF (FAMLINK). We will collect CPS and child welfare information up to 5 years after they finish the services provided by the study.

What the study involves for families:

- The study parent will receive one of two services designed to support families with young children:
 1. *"Promoting First Relationships®" (PFR)* is a 12-week home visit service with a parenting support specialist. Each visit would be scheduled at a time that is convenient for the parent and child, and will last about one hour. Parents would learn how to promote the child's healthy social and emotional development. The sessions will include time for the parent and child to play together; five of the play sessions would be videotaped. The specialist will watch the tapes with the parent, and offer positive feedback. The sessions will also focus on the deeper feelings and needs that can cause children's challenging behaviors. For this study, PFR has been adapted for older children (up to age 5), and expanded to include two additional sessions specifically designed to meet the needs of recently reunified parents.
 2. *"Resource & Referral"* is a service delivered to the parent over the phone. They would talk with a trained professional about their family's needs and receive individualized referrals to help them meet those needs. They would receive in the mail a Local Services Resource Packet containing information about services in their community. They would receive follow-up phone sessions once a month for three months, to check in with them and see if they would like any additional information. They would be able to contact the specialist at any time after their first session if they had any concerns or wanted additional referrals.
- The parent/child dyad will be put into 1 of the 2 groups (Promoting First Relationships® or Resource & Referral). They have a 50/50 chance (like a coin toss) of being in either group. After their first visit they will find out which group they are in.
- There will be 3 research visits with the parent and child. The first visit would be after they agree to participate. The second will be about 4-5 months later, when they are finished with the intervention. The third visit will be about 6 months later. These visits are to collect information for research. The visits include interviews, activities, and play time between parent and child. Parts of the visits will be videotaped and audio taped. The research visitors have passed criminal background checks.

What the research home visits involve (2 hours)

Free play: The parent and child will play with a set of toys. They will be asked to play as they usually do.

Teaching activity: The parent will choose an activity from a list that the child hasn't done yet. We will ask the parent to teach the child how to do it. It doesn't matter if the child actually does it.

Video viewing: The parent will watch a part of the free play and teaching activity videos with the research visitor. She will ask the parents questions about the video.

Parent interview: The parent will be asked about topics including the child's behavior, ideas about parenting, the parent's recent mood, current and past stressful events, and background information.

- Promoting First Relationships® and Resource & Referral services are provided by trained professionals. The parenting support specialists who do the PFR sessions are social workers and counselors who work for local agencies (Navos, ChildStrive, Answers Counseling) and the University of Washington. The Resource & Referral specialists and research visitors work for the University of Washington.
- Research visits will take place in the home at a time that is good for the parent and child. If they are in the Promoting First Relationships® program, the 12 weekly sessions will be in their home. If they are in the Resource & Referral program, the 3 sessions will be done on the phone.
- The study lasts about 12 months.

What are the possible risks or harms?

- The parent may feel that the questions we ask are an invasion of privacy. They may feel uncomfortable being videotaped. They may feel uncomfortable answering questions about themselves and their child. They may be uncomfortable releasing information about reports to CPS and their work with DCYF. To help them feel more comfortable, they may take a break at any time. They can refuse to do any study activity. They may end or postpone a session at any time.
- There is a small risk to their privacy. We will do everything we can to protect their privacy. Only the research team will see study information and videotapes. The tapes and papers will be kept in a locked University office. Only the research staff uses this office.
- If you, the child, or parent experience any problems with the study, we request that you or they contact one of the researchers listed on the first page of this form.

What are the possible benefits?

- The knowledge gained from the study may help families in the future because it will help us understand how each program works and what can make them better. It may increase our understanding of how to use these programs with other families.
- The parents will receive free services that may help them and their families. They may receive support and information about where to get services.

What if I don't give permission for the dependent child to participate?

- Being in the study is voluntary. You may refuse to allow the child to participate or withdraw him/her from the study at any time. The study is voluntary for parents too.

- You do not have to sign this form for the child to get services from DSHS or any other agency. You may decide to cancel your permission at any time. However, the child can receive the support services offered through this research *only* if you provide permission.
- If you withdraw the child from the study, we would still keep any information already collected from the child. But we would not conduct any further study activities involving the child.
- If you cancel your permission before the end of the study, the child will no longer be eligible for study services. But families wouldn't lose any other services or benefits.

Who would see study information about the child?

- Only members of the research team will be able to look at the tapes and paperwork. All materials will be stored in a locked file in Dr. Oxford's offices at the University of Washington. Code numbers and not names will be used on the questionnaires, videotapes, and paper work. Contact information will be kept in a locked file cabinet. Computer files containing research information will be secure, and will only include code numbers. We will destroy names, phone numbers, and research tapes by April 30, 2030, 6 years after the end of the study.
- The researchers will not give information about the study participants to anyone else. We will only use the information for our study.

Would the parent be paid for his/her time? Will the study cost the parent anything?

- The parent will receive \$75 in cash for each research visit. They would get a total of \$225 if they do all of the research visits.
- The study won't cost the families anything. Any study services are provided to the parent free of charge. The study will cover the cost of any services and materials they might receive.

What else do I need to know?

- If the child is removed from the home during the study: (1) They won't be eligible to get any more study services, and (2) They won't be eligible to take part in the research visits.
- We want to protect their privacy. To help us protect their privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify them 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 them, 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. 1) If we suspect that a child is being abused or neglected, we will report it to CPS. 2) If we find out that someone is thinking about harming him/herself or other people, we will call the Crisis Line, or the local police if there is immediate danger.

We will not share the child's or parent's study information from any of the visits with DSHS. Parents who complete study intervention sessions will receive session completion cards which they can choose to share with you; however, research staff will not provide this information.

- If you have questions about the study, you may call Dr. Oxford at 206-685-6107 or toll free at 877-705-2759.
- You may call the Washington State Institutional Review Board if you have questions about your, the child's, or the parent's rights or concerns/complaints about the research. The WSIRB oversees this study to make sure that the rights of people who take part are protected. You can call at 1-800-583-8488. You don't have to give your name if you call.

INVESTIGATOR SIGNATURE	DATE
If you agree to participate: The study described above has been explained to me. By signing below, I voluntarily consent for the child named below to take part in this research. I have been told that parents can refuse to answer any question or leave the study at any time, without penalty. I have had a chance to ask questions. I have been told that I may call the researchers if I have any questions about the research. I have been told that I may call the Washington State Institutional Review Board if I have questions about the child's, the parent's, or my rights or if I have concerns or complaints about the study.	
SOCIAL WORKER'S SIGNATURE	DATE
SOCIAL WORKER'S PRINTED NAME	
DEPENDENT CHILD'S PRINTED NAME	CHILD'S DATE OF BIRTH

Copies to: DSHS/Department of Children, Youth, and Families
Investigator's File



Families Together

Dr. Monica L. Oxford, Principal Investigator
206-685-6107 / 877-705-2759

Authorization for Use and Disclosure of Protected Health Information

I, _____, give permission for DSHS/DCYF to give
(Social worker's name)

a dependent child on my caseload's protected health information in his/her Child Welfare (CPS) records to Dr. Oxford, or to a member of her research team.

This authorization allows DSHS/Department of Children, Youth, and Families (DCYF) to disclose information about contacts with Child Protective Services (CPS), including dates of any reports, what the report was about, and what happened after the report. DSHS may release the records from the child's birthdate through 5 years after he/she finishes getting services from the Families Together program.

The child's protected health information will only be used for the study called Families Together. The researchers won't use it for any other reason. The researchers will keep his/her health information confidential. They won't give it to anyone who isn't connected to this study.

I'm not required to sign this form for the child to get services. DSHS/DCYF will only give his/her protected health information to the researchers if I sign this form. I may cancel this authorization at any time by writing to DSHS/DCYF. If I cancel this authorization, the researchers will keep the information they already have.

My privacy rights are described in detail in the DSHS Notice of Privacy Practices for Client Medical Information (available at <http://dshs.wa.gov>).

This authorization expires April 30, 2030 unless I cancel it before then.

PRINT STUDY CHILD'S NAME

STUDY CHILD'S DATE OF BIRTH

Social Worker

Signature

Date

cc: DSHS/DCYF, Researcher