Cover Letter

Randomized Controlled Trial of Prenatal Coparenting Intervention

(CoparentRCT)

NCT03097991

Parental Informed Consent Form

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UNIVERSITY OF SOUTH FLORIDA

Parental Permission to Participate in Research

Information for parents to consider before allowing your child to take part in this research study

IRB Study # Pro00021462

Researchers at the University of South Florida (USF) study many topics. To do this, we need the help of people who agree to take part in a research study. This form tells you about this research study.

The following information is being presented to help you decide whether or not your child wants to be a part of a research study. Please read carefully. Anything you do not understand, ask the investigator.

We are asking you to allow your child to take part in a research study that is called: Figuring it Out for the Child (FIOC).

The person who is in charge of this research study is Dr. James McHale. This person is called the Principal Investigator. However, other research staff might be involved and can act on behalf of the person in charge.

The person explaining the research to you may be someone other than the Principal Investigator. For this study, we'll first meet with your child today for some interviews. After today's interviews, your child will receive a call within 48 hours telling him or her whether he or she has been selected to participate in the study or not. If your child is selected to participate, your child will be randomly assigned to one of the two groups. One group, the Resource and Referral Program group, will receive access to our Resource and Referral Navigator who will help to connect your child with our community partners who specialize in services for pregnant women and their families. The other group, the FIOC Program group, will receive access to our resource and referral service and an opportunity to participate in a set of 7 meetings to discuss and help prepare for coparenting. Assignment to a group is random which means your child has equal chance of being placed in either group. Neither your child nor the study team members your child meets can choose what group your child will be in.

Most families selected to go on in the study after today will also be invited to complete questionnaires, to take part in family discussions, and to play together with the baby twice more after the baby comes, no matter which group they are in. Those visits will take place 3 and 12 months after the baby is born. Finally, even if your child is selected to participate after today, it is possible that your child may be discontinued from study participation at any point during the study. All of the study meetings will be held at one or more of the following locations, depending on which is most convenient for your child: USF St. Petersburg, Next STEPP Life Center or Johns Hopkins All Children's Hospital. Alternatively, some study meetings may be online study meetings, scheduled via the Microsoft Teams platform.

This study is sponsored by the National Institutes of Health.

Should your child take part in this study?

This form tells you about this research study. You can decide if you want your child to take part in it. This form explains:

- Why this study is being done.
- What will happen during this study and what your child will need to do.
- Whether there is any chance your child might experience potential benefits from being in the study.
- The risks of having problems because your child is in this study.

Before you decide:

- Read this form.
- Have a friend or family member read it. Talk about this study with the person in charge of the study or the person explaining the study. You can have someone with you when you talk about the study.
- Talk it over with someone you trust.
- Find out what the study is about.
- You may have questions this form does not answer. You do not have to guess at things you don't understand. If you have questions, ask the person in charge of the study or study staff as you go along. Ask them to explain things in a way you can understand.
- Take your time to think about it.

It is up to you. If you choose to let your child be in the study, then you should sign this form. If you do not want your child to take part in this study, you should not sign the form.

Why is this research being done?

The purpose of this study is to find out whether meetings designed to support young moms and dads who are expecting a first baby together helps them to work effectively together as parents after the baby is born. Not all moms and dads decide to get married or stay in a romantic relationship. But that does not mean that they cannot team together to coparent the baby and help the baby develop in a healthy and positive way. The goal of the study is to find out if pregnant moms and babies' dads think the meetings are helpful, and to see if the meetings help them parent effectively together after the baby comes.

Why is your child being asked to take part?

We are asking your child to take part in this research study because we want to learn more about how young children adjust during challenging times in their families' lives.

What will happen during this study?

There are 3 parts to the study if your child is assigned to the Resource and Referral Program group and 5 parts to the study if your child is assigned to the FIOC Program group .The first part is a visit involving your child and the baby's other parent. There will first be a one-on-one interview with each parent, and we will ask permission to audiotape this session. After your child and the other parent finish their one-on-one interview, they will spend time talking together about parenting ideas. I will

ask your permission to videotape this session. Please provide your initials below indicating agreement to allow us to videotape or not.

Yes_____ No_____

After today, your child and your child's coparent will receive a call within 48 hours. This call will tell your child whether he or she has been selected to participate in the study or not. If your child is selected to participate, your child will learn on the call whether he or she will be in the FIOC Program group or in the Resource and Referral Program group. You will have an equal 50% chance, like the flip of a coin, of being placed in either group. Families will not be able to choose what group they will be in, or to switch from one group to the other.

The second part -- **for those assigned to the FIOC Program group only –** will involve your child meeting individually with Mentors for 1 or 2 "get-to-know-you" sessions, followed by six meetings at one of the designated community locations. The "get-to-know you sessions will be one-on-one with your child and his or her Mentor, while the six meetings will involve both your child and your child's coparent. Those 6 sessions will focus on working to build good teamwork between the mother and father as parents. It usually takes about 10 weeks to finish the get-to-know you sessions and the 6 meetings, but we can sometimes finish this second part of the study in less time if that is helpful to the parents. We will ask permission to audiotape these sessions. Please provide your initials below saying whether you agree to let us audiotape or not if your child is chosen for the FIOC Program group.

Yes_____ No_____

The third part- **for the FIOC Program group Only**, takes place after the 6 meetings end. We will interview your child to ask him or her how he or she thought the meetings went.

Next, **for BOTH groups, the FIOC Program group and the Resource and Referral Program group,** your child will bring the baby in three months after he or she is born and again when your child's baby is 12 months old and take part in some interviews and discussions just like the ones we'll do today. There will also be a play session involving your child, the other parent, and the baby. I ask that we be permitted to videotape the family interactions during this meeting. Please provide your initials below indicating agreement to allow us to videotape or not.

Yes_____ No_____

Ongoing Contact during the Study

Episodically throughout the project, if you choose to provide your cell phone or your child's cell phone as contact information for scheduling of visits, you or your child will receive reminder texts in advance of upcoming appointments.

About 170 moms and 170 dads will take part in this project.

What other choices do you have if you decide not to let your child to take part?

If you decide not to let your child take part in this study, no services they currently receive will be denied to them.

Will your child be paid for taking part in this study?

We will compensate your child a total of $150 in gift cards for the time volunteered in the study if your child participates and completes all assessments. If your child is randomly selected to participate in the FIOC Group he or she will receive an additional $50 in gift cards if he or she completes the entire intervention.

For both the FIOC Program group and the Resource and Referral Program group: Your child will receive $25.00 after he or she completes the initial research interview session. Your child will receive $50 after the second research interview session 3 months after the baby is born. And your child will receive $75 after the third interview session 12 months after the baby is born.

For FIOC Program group ONLY:

- If your child is randomly selected to participate in the FIOC Program group and attend all 6 of the FIOC meetings, he or she will also receive a $50.00 gift card.

What will it cost you to let your child take part in this study?

It will not cost you anything to let your child take part in the study.

What are the potential benefits to your child if you let him/her take part in this study?

For those selected to participate in the FIOC Program group we hope the project will benefit your child by giving him or her an opportunity to learn how to team together better with their baby's other parent. When parents work well together as a team, babies show stronger development and adjustment. For those selected for the Resource and Referral Program group, we will help ensure that you are aware of and have access to the multitude of services available to prenatal and postnatal families in Pinellas County.

Risks or Discomfort

This research is considered to be minimal risk for both the FIOC Program Group and the Resource and Referral Program group. That means that the risks associated with this study are the same as what

your child will face every day. Some people report feeling a bit uncomfortable at first with videotaping or audio-taping procedures. If your child has any worries about these things at any point during the study, please tell me or the project staff member who is working with you. Though every attempt is made to minimize all risks and discomfort, additional risks or discomfort associated with this research study may include:

1. possible violation of confidentiality,
2. possible discomfort due to assessment procedures,
3. possible embarrassment in disclosing sensitive personal information,
4. possible disclosure of information about intended physical harm to victims or abuse/neglect of children that would need to be reported to the child welfare agency and an investigation of the allegations(s) and further action, as indicated, that could ensue,
5. possible disclosure of homicidal or suicidal thoughts, threats, ideation, attempts, or plans, requiring mandatory reporting if participants are at imminent risk of endangering themselves or others.
6. possible dissatisfaction with the assessment/intervention procedures.

It is unlikely your child will experience any of these situations but in the event that he or she does, project staff will be with your child to address any concerns, discomfort and to assist your child in getting additional services if needed. Your child may also discontinue your participation at any time during the study without adverse consequences to him or her.

Cost

There will be no cost for your child to participate in this study. If your child needs help with transportation fare to or from the sessions, we will schedule that for your child and pay the cost of the transportation.

What will we do to keep your child's study records private?

For all data and information collected after you and your child sign the informed consent/assent forms, whether your child is selected to participate in the study or not:

There are federal laws that say we must keep your child's study records private. We will keep the records of this study private by using the code numbers instead of names on all records and tapes, and by keeping the tapes locked at the USF St. Petersburg Family Study Center at all times while the study is ongoing. The key linking your child's name to this code number is kept only by the lead investigator, Dr. McHale, in a separate locked area of the Family Study Center so that no one else can link a name to a record. Because we do not write a name or put any other identifying information on the videotape, this means that the USF researchers have no way of knowing who your child is when they review the tape.

Though certain people besides the USF staff members may need to see your child's study records, by law, anyone who looks at your child's records must keep them completely confidential. The only people who will be allowed to see these records are:

- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your child's records. These include the University of South Florida Institutional Review Board (IRB) and

the staff that work for the IRB. Individuals who work for USF that provide other kinds of oversight to research studies may also need to look at your child's records.

- Other individuals who may look at your child's records include: agencies of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS),the Office for Human Research Protections and the study's sponsor-the National Institutes of Health (NIH). They also need to make sure that we are protecting your child's rights and safety.
- The USF Institutional Review Board (IRB) and its related staff, who have oversight responsibilities for this study, staff in the USF Office of Research and Innovation, USF Division of Research Integrity and Compliance, and other USF offices who oversee this research.
- The designated peer review committees such as the project's Data and Safety Monitoring Board who monitor the data and safety of the study.
- The only other situation in which we are required to share confidential information is if staff members discovered that there was 1) physical injury to any child caused by other than accidental means, which by law must be reported to authorities as required by Florida Statute 39.201; and 2) information from a study participant that led staff to believe a person is in imminent danger of physical harm.
- We have obtained a Certificate of Confidentiality for this study. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project.

We may publish what we learn from this study. If we do, we will not let anyone know your child's name. We will not publish anything else that would let people know who your child is.

At the end of the study, the videotape of the assessment completed with your child will be destroyed.

What happens if you decide not to let your child take part in this study?

You should only let your child take part in this study if both you and the child want child to. No one in the family should feel that there is any pressure to take part in the study to please the study investigator or the research staff.

If you decide not to let your child take part:

- Your child will not be in trouble or lose any rights he/she would normally have.
- You child can still get the same services he/she would normally have.

You can decide after signing this informed consent document that you no longer want your child to take part in this study. We will keep you informed of any new developments which might affect your willingness to allow your child to continue to participate in the study. However, you can decide you want your child to stop taking part in the study for any reason at any time. If you decide you want your child to stop taking part in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely. We will tell you if there are any dangers if your child stops suddenly. We do not anticipate that there would be any.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call Dr. James McHale at 727-873-4848.

If you have questions about your child's rights, general questions, complaints, or issues as a person taking part in this study, call the Division of Research Integrity and Compliance of the University of South Florida at (813) 974-5638.

If your child experiences an adverse event or unanticipated problem, call Dr. James McHale at 727-873-4848.

Consent for Child to Participate in this Research Study

It is up to you to decide whether you want your child to take part in this study. If you want your child to take part, please read the statements below and sign the form if the statements are true.

I freely give my consent to let my child take part in this study. I understand that by signing this form I am agreeing to let my child take part in research. I have received a copy of this form to take with me.

_____ _____

Name of the Child Taking Part in Study Date

_____

Printed Name of Parent or Guardian* of the Child Taking Part in Study

_____ _____

Signature of Parent or Guardian* of the Child Taking Part in Study Date

- Note: A guardian is someone who has been appointed by the court to serve in that role; if a child is in the custody of a temporary legal guardian, specific authority of the court will be required before the guardian can consent to the child's participation in research.

Statement of Person Obtaining Informed Consent

I have carefully explained to the adults taking part in the study what they can expect.

I hereby certify that when these individuals sign this form, to the best of my knowledge, they understand:

- What the study is about.
- What procedures/interventions will be used.
- What the potential benefits might be.
- What the known risks might be.

I also certify that they do not have any problems that could make it hard to understand what it means to take part in this research. They speak the language that was used to explain this research.

They read well enough to understand this form or, if not, were able to hear and understand when the form was read to them.

They do not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give informed consent.

They are not taking drugs that may cloud their judgment or make it hard to understand what is being explained and can, therefore, give informed consent.

_____ _____

Signature of Person Obtaining Informed Consent Date

_____

Printed Name of Person Obtaining Informed Consent