COVER PAGE

STUDY TITLE: Study of the Families Moving Forward Website Behavioral Intervention for Teachers of Students With Fetal Alcohol Spectrum Disorder

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UNIVERSITY of ROCHESTER

INFORMATION SHEET
Pilot Trial of the FMF Connect Teacher Companion Website
Principal Investigators: Christie Petrenko, Ph.D. and Cristiano Tapparello, Ph.D.

This form describes a research study that is being conducted by Christie Petrenko and Cristiano Tapparello from the University of Rochester.

The purpose of this study is to find out if the FMF Connect Teacher Companion website is acceptable and usable by teachers. The FMF Connect Teacher Companion website is a website for teachers adapted from the Families Moving Forward (FMF) Program. The FMF Program is an evidence-based intervention for caregivers of children with FASD.

If you decide to take part in this study, you will be asked to complete a series of questions to see if you meet the eligibility criteria. If you do not meet the eligibility criteria, you will be notified, and the study will end. If you do meet the eligibility criteria, you will be randomized to one of two groups. The first group will receive access to the website after completing the first round of surveys. The second group will receive access to the website in six weeks. After you are assigned to a group, you will complete the first round of surveys for the study. The first round of surveys will take about 10-15 minutes. If you are in the first group, you will receive access to the website after you complete the first round of surveys. You are encouraged to use the website as much as you would like.

We will briefly screen your IP address to help ensure data integrity. REDCap will assess your IP address to ensure the survey is completed only once. Your general location (city, state) will also be assessed at the beginning of the survey to ensure that you are located in the US. At the completion of the study, we will remove this identifier. You may also be asked to complete tasks that verify you are a human, like CAPTCHA.

After six weeks, you will fill out another set of surveys. You will receive an email notification when it is time to complete each set of surveys. This second set of surveys will take about 15-20 minutes. If you already have access to the website, you will be able to keep accessing it. If you do not yet have access to the website, you will get access after completing the second set of surveys. In another six weeks, you will complete a final round of surveys. This final round of surveys will take about 15-20 minutes. Some participants will be selected to complete an interview during either the second or third round of surveys. They will be selected based on certain characteristics like demographic data, their answers to the surveys, and how much they use the website. We are doing this to ensure we hear from a wide variety of people. If you are selected for an interview, and you agree to do it, you must agree to keep your video on during the interview to confirm your identity.

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We estimate that approximately 90 people will take part in this study. Your participation will last about three months.

Possible risks or discomforts of this study include a risk or boredom or discomfort while filling out the surveys. You may skip questions you do not want to answer. You are also able to take breaks when completing surveys. Regardless of how much you use the website, you can still be in the study. You may withdraw from the study at any time.

There are no other expected risks to you for participating in this study. There are also no guaranteed benefits. However, you may find the information on the website helpful. The alternative to participating in the study is not to participate.

The University of Rochester is receiving payment from the National Institute of Child Health and Human Development (NICHD) and a private donation for conducting this research study.

You will be paid $25 each time you complete the surveys (up to a total of $75). If you are selected for an interview, and you complete an interview, you will be paid an additional $25. You will not be paid for completing screening questions or for using the website.

For this study we use a subject payment system called Participant Payments. The system allows three ways to provide payment. You can choose: a reloadable debit card; direct deposit; or mailed paper checks. The study team will help you create a "subject profile" in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile**.** Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have a Participant Payments account (because you are in another study that uses this system), your existing profile will be used to provide payment. You will be sent the "Information Sheet for Participant Payments" which will include additional information.

Payment received for participation in research is considered taxable income. If you receive payment for your taking part in studies at the University of Rochester of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. You may be asked to submit a W-9 form, which includes your Social Security Number. If you are asked to complete a W-9 form and we find that you are not a US citizen or permanent resident, we may need to withhold 30% of your payment for taxes consistent with tax requirements.

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

You may be withdrawn from the study if the investigator suspects you may be falsely representing yourself as a teacher. You may contact the study team to verify your identity if you believe you are incorrectly withdrawn. You may also be withdrawn from the study if you behave inappropriately towards research staff or other subjects.

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will store your information, survey and interview responses, and any other data on secure computer systems at the University of Rochester. Your name will not be connected with your survey and interview data.

Sometimes, however, researchers need to share information that may identify you with people that work for the University. If this does happen, we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

The National Institutes of Health (NIH) issued a Certificate of Confidentiality (CoC) for this study. A Certificate of Confidentiality provides extra protection for you and any information collected from you as part of this study because it prevents us from disclosing this information in a lawsuit or legal proceeding. We cannot release your study information in a lawsuit or legal proceeding unless you provide your consent for us to do so. This is an extra layer of protection above the already existing protections in place for you and any information collected from you as part of this study. However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency funding this study requests the information, or if the FDA tells us to release this information. You should visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.
You will receive communications about this study via email messaging. We will use email to communicate with you about scheduling, reminders to complete surveys, payment, and about the interviews if you are selected to complete one. Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email or texting. Email communications between you and the study team may be filed in your research record.

Your participation in this study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefits to which you are otherwise entitled.

For more information or questions about this research you may call Christie Petrenko at 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.