**Feasibility Trial of the FMF Connect Mobile Health Intervention**

**Principal Investigators**
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## 1. PURPOSE OF STUDY

This study represents the second phase of a larger research project developed for a U01 award as part of the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD) funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The overall project aims to develop and evaluate a mobile health (mHealth) application (app) for parents/caregivers of children with fetal alcohol spectrum disorders (FASD).

The first phase of this project was approved under IRB protocol #1266 (legacy RSRB#67394). In that phase we used qualitative research methods to engage parents and caregivers in the development of the mHealth intervention and obtain iterative feedback on acceptability and feasibility. A prototype of the app was completed in both iOS and Android and beta-testing was completed with parents/caregivers and providers.

In this second phase of the study, we are aiming to conduct a larger feasibility trial of the app with 60 parents/caregivers. Data collection will include quantitative pre-post surveys and qualitative interviews with a subsample of users. Our hypothesis is that quantitative measures will show improvements in child behavior, parent FASD knowledge, parenting self-efficacy, behavior attributions, family needs met, and parent use of self-care. We also hypothesize parents/caregivers to rate app quality positively. These quantitative indicators are expected to correlate with patterns of app usage. This quantitative data will allow us to calculate pre-post effect sizes, which will inform needed sample sizes for the large-scale hybrid effectiveness-implementation randomized controlled trial (RCT) planned in phase 3 (IRB approval will be obtained prior to phase 3 implementation). Qualitative interview data will provide a rich context for the feasibility of the app and offer further insights into fine-tuning of the app and measurement battery prior to the RCT.

## 2. BACKGROUND AND RATIONALE

Children with fetal alcohol spectrum disorders (FASD) have significant neurobehavioral impairments that contribute to poor adaptive function and increased behavior problems in home, school, and community settings [1]. Most interventions for preschool and school-aged children with FASD, the largest age group with identified FASD [2], are directed at caregivers or have included parent training to facilitate child skill acquisition [3]. Interventions directed toward caregivers are an essential component of FASD integrated care models [3,4]. Tailored FASD-informed caregiver interventions provide families with the knowledge and skills to better understand their children's development and behavior, generate effective environmental accommodations and behavior plans, teach and generalize targeted child skills, and advocate for their children in school and community settings [3]. These strategies are vital for sustained child improvement and better family adaptation.

Unfortunately, we and others have documented that the vast majority of families cannot access FASD-informed interventions. Barriers to care occur because a knowledgeable and skilled workforce is lacking [5,6], and there are family-level barriers such as limited financial resources, inability to access childcare, and stigma [7]. Access to appropriate FASD-informed care is even more limited in less densely populated areas. Many families try peer-to-peer and self-help strategies, but it can be

difficult to evaluate the credibility and effectiveness of information provided through these modalities.

The primary objective of this project is to develop and evaluate an mHealth app to directly provide caregivers with evidence-based content and peer-moderated support they can easily access and use to improve outcomes for their children and families. The app, called "FMF Connect," will be derived from our work on the scientifically-validated Families Moving Forward (FMF) Program that has shown promising results for child and caregiver outcomes in three trials with families raising children with FASD [8]-[10].

This project will follow a systematic approach to the development and evaluation of the FMF Connect mHealth intervention. The app will be designed for use by caregivers, will utilize a cloud-based infrastructure, and will build on our existing open source framework for the development of medical apps [11], and those of others [12,13]. Preliminary feasibility tests and iterative feedback from diverse caregivers will aid in fine tuning caregiver instructions, content, and user-interface features throughout the development process. Core content will be provided to all users, with optional features tailored via needs assessment.

In this and subsequent phases, the FMF Connect mHealth intervention will be evaluated to identify the patterns of app usage that relate to the greatest improvements in child and caregiver outcomes. Consistent with prior FMF trials, targeted outcomes include satisfaction, child behavior problems, caregiver FASD/advocacy knowledge, attributions of misbehavior, parenting practices, parenting efficacy, self-care, and social support. This novel mHealth intervention has the potential to reach many families in need and reduce significant barriers to care, resulting in broader public health impact. Project findings will guide further app development both in terms of content and technological advances to optimize intervention effects.

## 3. ADMINISTRATIVE ORGANIZATION

This study will be conducted through the University of Rochester (UR) and will involve faculty, students, and staff within the following departments and centers: Department of Psychology, Mt. Hope Family Center (MHFC; which is a part of the Psychology Department), Department of Electrical and Computer Engineering (ECE). Dr. Petrenko's primary appointment is at MHFC and the Psychology Department. She oversees the study coordinator, research assistant, and graduate and undergraduate students working on the project within these departments. Dr. Tapparello is faculty within ECE and oversees staff and students within these departments contributing to the project. Weekly project lab meetings ensure coordination across all aspects of the project.

All data collection and communication with participants is completed by UR project staff. Consenting and screening data, contact information, and quantitative survey pre-post data will be collected and stored online using REDCap hosted by UR. Participant interaction with the app is recorded using Amazon Web Services (AWS; HIPAA-Compliant). Qualitative interview data will be gathered by research staff using HIPAA-compliant Zoom videoconference application. All paper and electronic files will be securely stored on MHFC servers and in locked cabinets only accessible to UR project staff.

As part of CIFASD, this study may involve data sharing as outlined by the policies and procedures established by CIFASD and required by NIAAA: https://cifasd.org/data-sharing/ . De-identified data will also be stored in the CIFASD Central Repository hosted at Indiana University (IU), as is required by NIAAA for all projects involved in CIFASD.

## 4. STUDY DESIGN

This study involves a single arm feasibility trial. Quantitative survey data will be collected prior to intervention delivery and 3-months later. App usage will also be recorded during the 3-month period. After 3 months, a subsample of participants will be selected to complete a qualitative interview about their experiences using the app. Primary study outcomes include child behavior, parent FASD knowledge, parenting self-efficacy, behavior attributions, family needs met, and parent use of self-care. We are also interested in participant perceptions of app quality and patterns of app usage.

## 5. SUBJECT POPULATION

The subject population will include parents and caregivers of children (ages 3-12) with fetal alcohol spectrum disorders (FASD) or affected by prenatal alcohol exposure (PAE) who live in the United States.

We are aiming to include 60 parents or caregivers with usable data in this study. We expect a portion of families will enroll in the study, but not complete assessments or install the app. In our initial beta-testing trials, 80% of families installed and used the app at least once. Unfortunately, given the COVID-19 pandemic, participation rates are trending lower than observed in prior trials. As a result, we will target 120 parents and caregivers in the trial.

It is also possible that interest in the study will exceed our intended final sample size. Given that informed consent procedures will occur online, we have set the number of subjects at 300. If enrollment quickly exceeds 120, we will utilize stratified random sampling with oversampling of a couple of underrepresented groups (i.e., biological parents, men).

- Strata may include region of the US, operating system (iOS vs. Android), or other variables depending on the number of participants and their relevant characteristics.
- We will plan to oversample any biological parents who enroll in the study (up to 20% of the sample, and then randomize any remaining with the rest of the sample after that), as their perspective is underrepresented in FASD research and they represent an important demographic for FMF Connect.
- We also plan to oversample male participants (up to 20%, and then randomize any remaining with the rest of the sample after that).

Families will be told in the consent document that they will be informed about future trials if they are not selected for the feasibility trial.

## 6. INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

- Biological parent or other primary caregiver (e.g., foster or adoptive parent, relative, legal guardian) of a child with FASD or PAE
- The parent/caregiver must be at least 18 years old
- The child must between the ages of 3 and 12 years old (if there is more than one child in the family with FASD/PAE in this age range, the parent/caregiver is instructed during screening to choose one to complete study surveys about)
- The child has a diagnosis of FASD or has confirmed PAE
- The child has lived with the parent/caregiver for at least 4 months and is expected to remain in the home for at least 1 year
- The parent/caregiver lives in the United States
- The parent/caregiver has a smartphone with iOS or Android operating system

Exclusion criteria:

- The parent/caregiver is not fluent in English (the FMF Connect app and pre-post measures are currently only available in English)

- There is another parent/caregiver of the same child or living in the home that is already enrolled in the study (couples are excluded to prevent dependence in the data)
- The family has previously received or is currently receiving the therapist-led Families Moving Forward (FMF) Program

## 7. RECRUITMENT METHODS

Potential participants will be recruited through a variety of mechanisms, consistent with previous studies in our research group and in CIFASD. The Study Website (www.fmfconnect.com) will include information about the study, as well as a link to the study REDCap Consenting and Screening Module for interested families to enroll.

Information about the study will be disseminated in various ways (see study flyer with link to the Study Website):

- Dr. Petrenko may share study information with eligible families in the RSRB-approved Future Contact Database (RSRB00055352; PI: Petrenko)
- Dr. Petrenko will share study recruitment materials with providers and community advocates who regularly see children with FASD
- CIFASD investigators can inform research participants or patients in their local sites or clinics for which they have routine access
- The National Organization on Fetal Alcohol Syndrome (NOFAS) is a member of CIFASD and has a mission to educate the public about FASD and disseminate research and policy information. They can disseminate the study flyer through their Weekly Round-Up newsletter, significant social media presence, and to their state and local affiliates who can share in their communities
- Dr. Petrenko and other CIFASD investigators may include slides about the study in conference or community presentations
- Organizers/moderators of popular social media groups can be sent the study flyer and can choose to share with their members

As part of CIFASD, we will also try to aid other projects with recruitment from our study sample. Our Consenting and Screening Module includes a question asking if participants are interested in learning about other studies. For those that indicate yes, we will send them any new relevant flyers or information about other consortium projects they might be eligible for. We will submit any flyers and email language in a modification to this study prior to sending to our participants. For example, the DiG Human Genetics Study within CIFASD has previously referred some families to our study. We would like to send their study flyers (see attached flyer and email language) to participants in our sample who indicated they have not previously done the DiG study (in Screening Module).

## 8. CONSENT PROCESS

Interested parents/caregivers will go to the Study Website to begin the informed consent process. On the Study Website they will select the link that they are interested in participating. This link will take them to the study REDCap Consenting and Screening Module, hosted at UR. Interested participants will have the option to review study consent information by video or text. They are also told they can contact the study team by phone or email to complete the consent process over the phone/video chat if they prefer (the research team would send them the consent and then go over it by phone/HIPAA-compliant video chat; participant would return signed copy).

- **Text option**: the text of the Consent document will be presented on the screen for potential participants to read. The Consent document will include the HIPAA authorization.
- **Video option**: the animated video reviews key details from the Consent document. The HIPAA authorization, and information about email and texting the research team are presented

following the video in text.

For either option, participants will need to answer several questions about the study to ensure comprehension. Participants will also be asked to indicate if they have questions and space will be provided for them to type in any questions they have. If the participant selects "yes" they have questions, they will be informed the study coordinator will contact them before they proceed. The study coordinator's contact information will also be presented if participants want to contact the coordinator with questions while reading the document.

If they don't have questions or the coordinator has addressed them, participants can sign the consent form by utilizing REDCap's signature field. Questions asking for first and last name and date of birth are included as extra documentation of the participant's identity. They participant will then select "Next Page" and a read only copy of the consent will be generated that they can review, download, and/or print. At the bottom of the page they will need to select "I certify that all the information in the document above is correct, and I understand that signing this form electronically is the equivalent of signing a physical document." Once this is selected they will be able to submit the signed consent form.

Upon completion of the consent survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository in REDCap (to allow for versioning). The e-Consent Framework in REDCap also records the IP address of the participant and displays this information in the file repository in order to help regulate potential duplicate forms from a single IP address. A PDF file of the completed consent form will be available for download by the user. The PDF can also be emailed to participants or printed/sent to participants in the mail on request if they are unable to open or save a copy electronically on their device.

Completion of the study consent document also triggers an automatic notification to the study coordinator, who will log-in to REDCap and review the consent. She will document the date of this review in the study database.

After completing the consent document, participants will answer screening questions to assess eligibility for the study (see Screening Form). If eligibility criteria clearly aren't met (e.g., out of age range, outside the US, no smartphone, etc), parents/caregivers will be informed immediately that they aren't eligible and the module will end. For parents/caregivers who appear to meet criteria or in cases where parents/caregivers answer "unsure" for any of the questions, contact information will then be gathered. Contact information will also include necessary variables to generate their "globally unique identifier" (GUID), which is used in other CIFASD studies (https://nda.nih.gov/s/guid/nda-guid.html).

Common variables are used across several CIFASD studies. We have adapted and streamlined several CIFASD Common Forms for the purposes of this study, which will be administered next in REDCap. These forms include: the Parent Demographic Form, the Child Demographic Form, the Prenatal Exposure History, and the FASD Diagnosis History forms. These forms take about 15 minutes or less to complete in total.

Some interested parents/caregivers may have already completed the CIFASD Common Forms through another CIFASD study. To reduce participant burden, participants will be asked prior to completing forms if they have done any of the other current CIFASD studies. If they answer yes, REDCap will be set up to have them skip out on completing the Prenatal Exposure History and FASD Diagnosis History forms. The CIFASD Common Forms for that participant can then be located in the CIFASD Central Repository by their GUID. In the event that a participant answers "yes" to other CIFASD studies, but their data cannot be located (e.g., is not deposited yet, difficulties creating a

GUID due to inconsistent data across studies), we will send participants our forms to complete via REDCap. Logistically, this may require changing their imputed response to "no" to release the forms in REDCap; this change will be documented to file.

After completing the Consenting and Screening module, participants will be notified that project staff will review all submitted information to assess final eligibility. They will also be reminded of the randomization procedures if interest in the study enrollment exceeds targeted sample size.

This study is funded by the National Institute of Health (NIH). A Certificate of Confidentiality is automatically included as part of the notice of award. Language regarding the Certificate of Confidentiality is included in the consent form.

## 9. STUDY PROCEDURES

**Data Collection Procedures**

Parents/caregivers who are selected for the study will be sent an email inviting them to complete the baseline study surveys (see survey battery below) administered by REDCap. Any families not selected (either due to ineligibility or not enough available slots) will be informed of their status. Eligible families not selected will also be told that they will be notified when any subsequent intervention trials of FMF Connect are initiated. They can consider at that time if they might like to participate.

Once the baseline surveys are completed, parents/caregivers will receive instructions via email of how to install the FMF Connect app on their phones (see instruction documents and accompanying emails). After three months, parents/caregivers will receive an email with a link to the follow-up surveys (see survey battery below). The assessment battery is estimated to take 35-45 minutes to complete at each timepoint.

**Table 1. Quantitative Study Battery**

| Measure | Baseline | Follow-up |
|---|---|---|
| Eyberg Child Behavior Inventory (5-8min) | X | X |
| Parenting Sense of Competence Scale (3-5min) | X | X |
| Family Needs Questionnaire (3-5min) | X | X |
| Knowledge & Advocacy Questionnaire (15-20min) | X | X |
| Self-Care and Support Assessment (3-5min) | X | X |
| Adverse Childhood Experiences (2 min) | X | |
| Family Background & Services Survey (5-10min) | X | X |
| COVID-19 Experiences Survey (5 min) | | X |
| User Version of the Mobile Health Application Rating Scale (5-8min) | | X |

Given lower response rates, participants who do not complete the follow-up surveys after receiving the automatic reminders in REDCap will be asked if they are willing to just complete the COVID-19 Experiences Survey. This will provide important data to help us understand how much COVID-19 impacted app usage and study engagement. This will also inform the future RCT design and measurement.

A subsample of participants (up to 30 parents/caregivers) will be invited to complete an individual interview or focus group after completion of the 3-month follow-up assessment. These participants will be selected based on diverse patterns of app usage and other participant characteristics.

The questioning route for interviews/focus groups will cover the following topics: 1) overall

impressions of the FMF Connect app; 2) experience using the app (both facilitators and barriers of use); 3) satisfaction and feedback on individual components of FMF Connect; and 4) perceived impact on self and family. Interviews/focus groups are expected to take about 60-90 minutes each. Audio recordings of interviews/focus groups will be transcribed for later analysis.

**FMF Connect mHealth Intervention**

The FMF Connect intervention includes cloud infrastructure and an innovative, multilayered mobile app. It incorporates tailored content for parents/caregivers of children (ages 3-12) with FASD or PAE. The app integrates five main components: 1) Dashboard; 2) Learning Modules; 3) Family Forum; 4) Library; and 5) Notebook. Weekly emails are also sent to support motivational engagement.

App education, derived from the standard FMF Program, is packaged in easily digestible Learning Modules. The Learning Modules are organized into three levels: 1) Getting Started; 2) Taking Action; and 3) Taking It to the Next Level. Each level is presented incrementally, with content in the subsequent level being made accessible once core content from the prior level has been viewed. The Library provides access to additional optional content that can be downloaded and printed to use in advocacy and skill development. The Notebook is a personalized section that organizes parents'/caregivers' responses to learning activities in a convenient location for later easy access.

The Family Forum serves to 1) engage and facilitate parents'/caregivers' continued utilization of the app, 2) support and extend parents'/caregivers' implementation of new knowledge and skills, and 3) provides peer support, encouragement, and understanding of the parent's/caregiver's own needs. Trained peer moderators will moderate discussion in family forums to ensure safety. They will also provide support and prompt skills or content areas to consider.

The Dashboard displays parent/caregiver progress in Learning Module completion, use of the Family Forum, and daily and weekly ratings imputed by the parent/caregiver. It also includes the Tip of the Day feature.

Complementing the app is a Cloud infrastructure to transparently but securely distribute information, including storing and retrieving data, managing notification and messaging, and synchronizing data on all devices. A local datastore will protect the mobile app against network failures and connectivity issues. This local datastore will be transparently synchronized with the Cloud database so that all the querying and security features will be always available regardless of network connectivity. Updates will be automatically pushed out so users have the latest version.

## 10. AUDIO/VIDEO RECORDINGS

Qualitative interviews will be recorded using the HIPAA-complaint Zoom videoconference application hosted by UR. Zoom allows users to join with audio and/or video using their computer and/or their phone. Audio and video recordings are downloaded immediately following the interview and saved to the secure servers at MHFC or UR supported Box (UR Zoom settings do not provide storage; they can only be saved locally). Only project staff will have access to these recordings. Recordings will be maintained indefinitely.

## 11. RISKS TO SUBJECTS

### Risks to Subjects

Participants may experience psychological risks associated with participation in this study, such as discomfort or boredom in answering questions or providing feedback about the app. Psychological discomfort is also possible during interactions between participants as part of the Family Forum of the FMF Connect app. This potential risk of discomfort is expected to be similar to other social media use.

There is also a risk of loss of confidentiality. All data collected for the proposed research study will be kept confidential to the extent allowed by law. Although it is unlikely given the nature of this study, if participants disclose that someone is being maltreated or is a danger to self or others, research staff will need to break confidentiality to make a report to the appropriate authority to ensure safety, as mandated by law. The Peer Moderators in the Family Form will be trained to promptly alert Dr. Petrenko if there are concerns about a participant or their family's well-being so she can take appropriate steps, which may include alerting outside authorities to ensure safety. It is also possible that other parents/caregivers in the Family Forum might disclose personal information about other participants who post in the Forum to people outside of the research studies. We believe that all identified risks are reasonable given the proposed procedures for protecting against risk.

**Protections Against Risks**

To minimize risk associated with psychological discomfort during surveys and interviews, participants will be given the option to skip questions they feel uncomfortable answering. The Peer Moderators in Family Forum will be trained in creating a welcoming, nonjudgmental, and supportive environment for all participants. Clear rules and expectations will be delineated for the Peer Moderators and participants. Participants will be notified of these rules and expectations upon receiving the FMF Connect app and will be reminded throughout their participation. Any violations of these rules and expectations will be addressed by the Peer Moderators (e.g., removing posts, alerting Dr. Petrenko). These violations will also be reviewed by Dr. Petrenko during supervision with the Peer Moderators. Participants will also have the ability to send an email to project staff if they experience discomfort during their participation in the Family Forum. Appropriate actions will be taken under Dr. Petrenko's supervision to address discomfort and participant well-being and safety. Participants can also choose to not enter or post in the Family Forum if they do not feel comfortable or are not interested in this component.

Multiple procedures will be implemented to protect participant confidentiality. In terms of data storage and management, all hard copy data (e.g., notes during qualitative interviews), will be secured in locked file cabinets within locked offices, available only to program staff. Electronic data (e.g., digital audio recordings and transcripts from interviews) will be stored in secured servers, and only program staff with knowledge of the password will be able to access the data. Forms with identifying information will be separated from the data collected and only subject numbers will be retained in data analysis files.

Multiple levels of protection will be put in place to reduce the risk of loss of confidentiality for data collected through the app. A local datastore will protect the mobile application against network failures and connectivity issues. This local datastore will be transparently synchronized with the Cloud database so that all the querying and security features will be always available regardless of network connectivity. Collected data will be stored using a random code that will not allow direct identification of a particular subject, while any data that identify the user will be stored separately. All the connections between the mHealth app and the Cloud, as well as access and storage to the Cloud database, will use state of the art authentication and encryption algorithms (e.g., HTTS, SSL and TLS). These were built and are managed by Dr. Tapparello. As a result, users will be able to add and modify their own data but will be prevented from viewing and modifying other users' data. FMF Connect will also not alter the security settings of the user's phone, access stored information in the phone, or access device functionalities without explicit user consent. A passcode (or touch ID/Face ID) will be required to access the content of the FMF Connect app, and all the personal data stored by the app will be encrypted automatically whenever the device is locked.

All information obtained for research will be kept strictly confidential (as allowed by law) by

research staff. Participants will be told about all exceptions (e.g., child/dependent adult abuse, harm to self or others) to confidentiality during the consent process. Project staff and the Peer Moderators will be closely supervised by Dr. Petrenko and instructed on confidentiality, including what information is confidential, the limits of confidentiality, and to whom to report concerns. If maltreatment is suspected, staff will first discuss their concerns with the caregiver and inform him/her that, as indicated in the consent form that she/he had previously signed, our staff are ethically and legally obligated to file a report with Child Protective Services. We have found that this approach conveys respect for the family and mitigates parental anger that might otherwise emanate from filing a report. In our experience, when situations requiring filing a maltreatment report are handled sensitively and framed as stemming from concern for the welfare of the entire family, caregivers often perceive the process as being helpful to them.

Finally, while it is not possible to control what participants do outside of group settings (e.g., Family Forum), we will thoroughly explain the concept and importance of confidentiality and give real life examples of what is appropriate and inappropriate to discuss with people outside of the project. The Peer Moderators will emphasize the importance of confidentiality and will monitor and remind families of this rule and expectation. Privacy settings within the Family Forum will balance participant confidentiality and caregiver preferences. All caregivers will be assigned a unique username to log into the app. They will also be able to select their own username that will show up in the Family Forum, which does not contain personal identifying information. These usernames will be separate from their research participant ID numbers. Participants will be informed of the risks to confidentiality at the outset of the study and will be provided with reminders. Caregivers will have the ability to choose how much information to share about themselves and their experiences in the Family Forum. No other data from other app components will be shared in the Forum, unless the caregiver independently and voluntarily elects to do so.

The FMF Connect intervention is viewed as a "value-added" intervention. Participants can continue to receive care as usual in their community. The alternative to participating in this study is not to participate.

## 12. POTENTIAL BENEFITS TO SUBJECTS

Parents and caregivers may not experience any direct benefits from participating in this study. However, participants in prior FASD research studies at MHFC have commented on how they value and derive personal satisfaction in participating in research to increase knowledge about this under-recognized condition and effective strategies to benefit other children and families. It is also possible, although not guaranteed, that participants might derive benefit from receiving the FMF Connect program. Possible benefits may include increased knowledge about FASD and parenting strategies or social support from other caregivers.

## 13. COSTS FOR PARTICIPATION

There are no costs to participate.

## 14. PAYMENT FOR PARTICIPATION

Parents/caregivers will receive a $40 electronic gift card each time after completing the baseline and follow-up surveys. If selected, parents/caregivers will receive $20 for completing a qualitative interview.

Participants who did not complete the follow-up survey battery, but were willing to complete the COVID-19 Experiences Survey will receive a $5 gift card.

## 15. SUBJECT WITHDRAWALS

Subjects will be advised during the consent process that they have the right to withdraw from the study at any time without prejudice. They can choose to use app as much as they want (or not at all). We are interested in obtaining pre-post survey data as well as feedback about the user experience from as many participants as possible, including those who chose not to use the app or found it hard to navigate. This information is useful in identifying ways to improve the app and facilitate user engagement. Subjects can choose not to complete any or all of the study assessments. They can also completely withdraw from the study with no future contact if they choose. In this case, any data they have previously provided may be used in analyses.

## 16. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

All data will be used solely for research purposes and will be securely locked in designated file cabinets, secure data servers at MHFC, Project REDCap database, and an encrypted, HIPAA-complaint Cloud database (for data collected via the app; see above). Identifying information will be stored separately from other data, which will be stored by research ID number. Multiple procedures will be implemented to protect participant data collected through the app, which are further detailed in the section "Protections Against Risks." Participant user names in the app will not include personally identifying information and will be distinct from their research subject number. Only senior key personnel and project research staff will have access to the data.

Written transcripts of qualitative data will omit any identifying information provided by participants during audio recorded interviews. For publication, any quotes utilized to provide evidence for a theme will be de-identified. Findings will be discussed in aggregate.

Consistent with the mission of CIFASD, the CIFASD Data Repository allows for data sharing for internal CIFASD investigators across projects as well approved external investigators. A CIFASD Data Sharing Policy has been established and is available on the CIFASD website: https://cifasd.org/data-sharing/. External investigators need to submit a CIFASD Data Access Request Form, CIFASD Data Use Agreement, and provide documentation of IRB approval.

## 17. DATA / SAMPLE STORAGE FOR FUTURE USE

As a CIFASD project, de-identified data from this project will be stored indefinitely in the CIFASD Central Repository, as required by CIFASD and NIAAA. The Central Repository is hosted and managed at Indiana University. Policies and procedures associated with the CIFASD Central repository are described in the prior section. Also, since data are associated with a GUID they can be aggregated with other studies with overlapping participants.

All data (de-identified and identifying) will be securely stored locally for an indefinite period. De-identified and identifying information will be stored separately as detailed above. Novel research questions may arise in the future that this important dataset could answer. Future studies may also be interested in long-term follow-up of families who participated in this research. Retaining identifying information would facilitate contacting families (subsequent to new IRB approval) to see if they would be interested in participating in follow-up research. MHFC has well-establish data security procedures in place for long-term storage and maintenance of data. Only approved project staff will have access to data.

## 18. DATA AND SAFETY MONITORING PLAN

Because the research involves the provision of a mobile health parenting intervention for parents and caregivers, the risk for a serious adverse event due to provision of the intervention is low. Adverse events that could occur in children with FASD or their parents/caregivers could include aggression or violence towards others, maltreatment, self-harm or suicidality, or the need for inpatient hospitalization. However, these occurrences are unlikely to be a direct consequence of participation

in the proposed research or interventions.

Dr. Petrenko will assume ultimate responsibility for the safety and well-being of research participants and the integrity of data collected. Dr. Petrenko has conducted several RCTs pilot feasibility studies with children and teens with FASD and their families. She is a licensed psychologist in the state of New York and is involved in other clinical and research activities at MHFC where maltreatment and suicidality are commonly reported.

The well-being of participants will be monitored throughout the course of the proposed research. If there are concerns regarding a participant during interactions with research staff, staff will immediately contact Dr. Petrenko for consultation and a plan will be developed to address the concerns raised.

The Peer Moderators will be trained to contact Dr. Petrenko immediately about any significant concerns that arise during their interactions with participants in the Family Forum. Additionally, because MHFC provides other treatment programs, there are other back-up clinical supervisors available for consultation for immediate needs. A phone tree will be established, similar to other projects at MHFC, and will be provided to the Peer Moderators. Dr. Petrenko will meet with the Peer Moderators weekly during the feasibility test to provide supervision and will assess participant well-being. Dr. Petrenko will consult with other co-Investigators and clinical staff at MHFC, as appropriate, to address participant well-being concerns.

An independent safety monitoring board has also been established for the larger project, consisting of researchers and clinicians with relevant expertise with at-risk populations, clinical trial monitoring, and human subjects protections and technology. ISM members and their areas of expertise are listed in the following table:

| Name | Title & Affiliation | Relevant Areas of Expertise & Experience |
|---|---|---|
| Fred Rogosch, Ph.D. | Research Director & Senior Research Associate, Mt. Hope Family Center, University of Rochester | Clinical psychologist; developmental psychopathology; risk and resilience factors; child maltreatment; long-standing member of UR Research Subjects Review Board; has served on prior DSMBs for high risk studies at MHFC |
| Sheree Toth, Ph.D. | Director & Professor, Mt. Hope Family Center, University of Rochester | Clinical psychologist; developmental psychopathology; relational interventions; maternal depression; maltreatment; prevention of teen depression; has conducted multiple large-scale intervention trials with high-risk populations. |
| Lynn Cole, M.S. PNP | Clinical Director, Kirch Developmental Services Center, Neurodevelopmental and Behavioral Pediatrics, University of Rochester Medical Center | Pediatric nurse practitioner; physical and mental health of children with developmental disabilities; intellectual disability, FASD, autism, and cerebral palsy. |
| Anthony Pisani, Ph.D. | Associate Professor in Psychiatry and Pediatrics, Center for the Study and Prevention of Suicide, | Clinical psychologist; suicide prevention; public health messaging; safe and ethical use of technology in prevention science |

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| | University of Rochester Medical Center | |

The ISM committee will review and suggest modifications to research protocols and consent documents to assure scientific integrity and adherence to human subjects' protection policies. They will meet with the PI and co-Investigators twice a year to monitor safety issues and provide feedback on scientific and ethical issues relating to project implementation. The IRB will be notified immediately of any adverse events via telephone and submission of a "University of Rochester Serious Adverse Event Report". Such events would also be reported to NIAAA. The proximity of committee members will also facilitate their ability to monitor data management activities. The committee may ask to review data for quality control purposes.

Ethically, we are committed to ensuring the welfare of children and their families. Any significant mental health or safety issues detected during the conduct of this investigation will be discussed with participants and options for the receipt of services presented. The FMF Connect app will also contain a module with links for mental health and crisis resources, as an additional safeguard. A safety message will also be included in the app to direct caregivers to call 9-1-1 or other local crisis services in the event of an emergency.

## 19. DATA ANALYSIS PLAN

**Aim 1: Pilot the Pre-Post Assessment Battery and Estimate Intervention Effect Sizes**

Descriptive statistics and reliability indices will be calculated for all measures at each time point. Analysis of Variance (ANOVA) techniques and effect size calculations will be used to estimate the magnitude of intervention effects. These analyses will inform power analyses for the future large-scale RCT and refinement of the measurement battery.

Additional correlational and regression analyses will also be undertaken to get a preliminary sense of how outcomes relate to patterns of app usage.

**Aim 2: Evaluate the Feasibility and User Satisfaction with FMF Connect**

Transcripts from qualitative interviews completed with selected parents/caregivers 3-months after accessing the FMF Connect app will be analyzed thematically [14] to understand their experiences using the app intervention. Specifically, 'first-level coding' will be undertaken by members of the research team to identify key ideas and common themes expressed by parents/caregivers. Identified themes will then be discussed and operational definitions determined. 'Second-level codes' are generated and a preliminary thematic framework is established. Interviews are then independently recoded to assess fit with the framework and identify confirmatory and disconfirmatory evidence for the model. Matrices are also often utilized to systematically examine relationships among constructs or assess model fit across participants. Agreement among team members on the analytic model is iteratively assessed and discrepancies resolved through further discussion, model refinement, and consensus. These analyses will inform app fine-tuning prior to the large-scale RCT planned in phase 3.

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