PROTOCOL TITLE:

Parent Acceptance and Commitment Therapy (PACT) for Parents of Children with Pediatric Feeding Disorder

PRINCIPAL INVESTIGATOR:

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	5/2/23	Changes per IRB request	Y
2	2/8/24	Change in exit interview	Y

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STUDY INFORMATION

1.0 Study Summary*

This is a pilot study of randomized clinical trial of Parent Acceptance and Commitment Therapy vs. an attention-control condition (placebo) for improving the mental health of parents of children with pediatric feeding disorder. The primary aims of this study are to evaluate feasibility and proof-of-concept.

2.0 Objectives*

2.1 Purpose, specific aims or objectives: Primary Aim: Test the hypothesis that PACT will result in clinically meaningful reductions in Mental Health(MH) problems among parents of children with Pediatric Feed Disorder (PFD) and identify factors that impact the feasibility of intervention delivery. This pilot study will involve conducting recruitment procedures for 4 months (or until parent N=30). Participants will be parents of 2- to 6-year-old children with PFD in outpatient treatment for their PFD. Parents will be randomly assigned to PACT or an attention control condition (control). Secondary aim: Test the hypothesis that PACT-F will result in clinically meaningful improvements in parent use of positive behaviors at meals, as measured through an observation of a representative mealtime.

2.2 Hypothesis: We will test the hypothesis that PACT results in clinically meaningful change in parent stress and anxiety, and parent use of positive mealtime behaviors, using the Reliable Change Index (RCI; success defined as RCI > 1.96). We anticipate that these procedures will be feasible, with feasibility success defined as recruitment rate above 60%, and retention, assessment completion, and intervention completion rate above 80%. Mixed methods data collection will identify factors that impact 1) recruitment rate (qualitative surveys, % meeting inclusion criteria, # of contact attempts), 2) retention rates (qualitative surveys, baseline characteristics; treatment group), 3) assessment completion rate (qualitative surveys, measure type), and 4) treatment completion rate (qualitative surveys, scheduling, treatment location).

3.0 Background*

Pediatric Feeding Disorder (PFD) is Prevalent, and Parents are Critical to Treatment Success. One-third of young children, and up to 80% of children with developmental delays, experience pediatric feeding disorder (PFD).[1] PFD is characterized by severely restricted volume or variety of foods and place children at increased risk for malnutrition.[2,3] PFD is also associated with high financial burden.[6] Interdisciplinary care to address medical and behavioral components of PFD is essential,[33,34] and often involves a physician, psychologist, dietician, and speech or occupational therapists.[18] However, treatment success relies on the implementation of treatment recommendations at home by parents, including structured family meals, positive parent-child interactions at mealtimes, and use of behavioral strategies to reinforce feeding behaviors.[35]

PFD is a Stressor to Parents. Many parents report distress when their child does not eat well as feeding is essential to survival.[19] Each meal, then (occurring 3-5 times a day), is a

potential stressor for parents of children with PFD. Many parents report "battles" with their children at mealtimes over eating.[19] Parents across the spectrum of child age report similar experiences of mealtime distress.[12,19,46]

Parents of Children with PFD are at Higher Risk for Mental Health (MH) Problems. Parents of children with PFD are at much higher risk for mental health (MH) problems (depression, anxiety, parenting stress, posttraumatic stress) than their peers,[7-14] with up to 40% of parents endorsing MH problems.[12] In qualitative interviews, parents report an enduring emotional impact,[19] including that difficulties feeding their young children negatively impacts their identity development as parents.[19] This emotional impact has also been observed biologically, as one study found increases in parent cortisol when feeding their child with PFD.[47]

Parent MH Problems Impact Health and Feeding Among Children with PFD. Parent MH problems are closely linked to poorer health outcomes in children with medical conditions such as poorer child quality of life, adherence to medical treatments, and mental health.[48-56] Parent MH problems have been explicitly linked to problematic child feeding practices.[15-17] Further, according to the child positive health model,[57] an innovative model for understanding child health, ecological systems[58] such as family factors shape child health. Thus, parent MH problems are critical to consider in relation to child health.

Parent-Focused MH Interventions May Improve Child Outcomes, but Uptake in Clinical Settings is Poor. Both pediatric feeding experts and parents have highlighted the need for interventions that specifically address parent MH problems in this population.[18,19] Multiple recent studies have achieved promising results when testing the efficacy of psychological interventions (using Cognitive Behavioral Therapy & Problem Solving) for parent MH in other medical populations such as cancer.[20] However, these interventions are typically time and resource intensive (e.g., 6-12 sessions). Even among oncology care, where national standards[25] have declared that parent MH should be addressed with all families, uptake of evidence-based parent MH treatments are low.[25] Therefore, brief interventions that require minimal resources are essential.

Acceptance and Commitment Therapy (ACT) has the Potential to Radically Improve the Uptake of Parent MH Interventions and is Therefore Ideal for Parents of Children with PFD. ACT is a transdiagnostic treatment approach that is effective in treating a wide range of adult MH problems. Emerging studies have found it can be effective in as few as one session.[27] ACT focuses on changing how a person perceives and responds to negative thoughts and feelings, rather than focusing on challenging and eliminating these thoughts and feelings which can be more time intensive. ACT recently was adapted for parents of children with neurodevelopmental disorders (PACT), and a series of pilot studies found that PACT meaningfully reduced parent depression and anxiety, and improved child behavioral outcomes, in just 2-sessions.[21,26,27] However, PACT has never been tested in a PFD population (nor has it been tested for problems other than anxiety and depression). If effective with parents of children with PFD, this brief treatment could radically increase the potential for uptake of parent MH treatment in PFD treatment clinics nationally.

Treatment Adaptations and Feasibility Testing are Critical Next Steps. In order to optimize the treatment for parents of children with PFD, our team has adapted PACT to meet the needs of parents of children with PFD using formative research methods (IRB# 00002321). Feasibility testing and proof-of-concept testing are the essential next steps before proceeding to an efficacy study.

4.0 Study Endpoints

Parents will complete the standard study battery at baseline, post-intervention, and 3-month follow-up.

Quantitative Measures. Feasibility success is defined as recruitment rate above 60%, and retention, assessment completion, and intervention completion rate above 80%.

Demographics. Parents will provide information on their own and child's age, sex/gender, race/ethnicity, education, and socioeconomic status.

- Parent Mental Health (MH) Measures.
    - PHQ-9. A 9-item self-report measure of depressive symptoms. Scores of 10 or more indicate probable depression.
    - GAD-7. A 7-item self-report measure of anxious symptoms. Scores of 10 or more indicate probable anxiety.[87]
    - IES-R. A 22-item self-report measure of posttraumatic stress symptoms. Scores of 33 or more indicate clinically significant posttraumatic stress.
    - PSS. A 10-item self-report measure of perceived stress. Scores of 14 or more indicate clinically significant stress.
    - AAQ-2. A 7-item self-report measure of psychological flexibility and experiential avoidance, which are targets of the behavioral treatment.
- Child Health.
    - PedsQL 4.0 (Generic). A 23-item parent-proxy measure of child quality of life, with versions specific to child age (2-4 years, 5-7 years) that each result in standardized total scores and domain-specific scores of physical functioning, emotional functioning, social functioning, and school functioning.
    - BPFAS. A 35-item parent-proxy report of child mealtime and feeding behavior.
- Qualitative Measures. Qualitative sruveys will be completed by parents at the 3-month follow-up, focused on factors that impact feasibility. Feasibility of 1) recruitment procedures, 2) intervention procedures, and 3) measure completion.
- Observational Behavioral Coding. Parents will record a representative family mealtime over Microsoft Teams at baseline, post-intervention, and at 3-month follow-up. A research assistant will facilitate the recordings over Microsoft Teams using procedures routinely employed in Dr. Davis's prior RCTs. The recordings will be coded using the Dyadic Interaction Nomenclature for Eating (DINE) coding scheme. The DINE is a well-established measure of mealtime behavior that has been studied in a variety of populations and has good psychometric properties.[74] The DINE measures parent-child interactions by coding three subscales: parent behaviors, child behaviors, and child eating behaviors. DINE coding will be completed by research assistants trained by the PI. The research assistants will be blinded to the intervention condition. Each video will be double-coded, and discrepancies will be resolved by meetings between the two coders and consultation with the PI.

5.0 Study Design*

Study Design. This feasibility pilot study.

6.0 Study Intervention/Investigational Agent*

Active Treatment (PACT-F) and Control Interventions*.* Parents randomized to PACT-F will complete two 90-minute PACT-F sessions individually with a study interventionist, 2-weeks apart. Parents randomized to the control group will complete two 90-minute sessions individually with a study interventionist, 2-weeks apart (focused on nutrition education). The control intervention will be parallel

to the PACT-F intervention, equal in the number of interactive components and duration of face-to-face time with health professionals (interventionists). Interventionists for both conditions will be individuals with at least master's-level training in mental health or a related field. Based on guidance from our parent consultants, we will deliver intervention sessions through Microsoft Teams to reduce barriers to participation (e.g., travel, childcare).

PACT-F. PACT-F is a 2-session intervention based on the Focused Acceptance and Commitment Therapy treatment literature[14,30] and the two-session PACT approach utilized by Brown[16] and Whittingham[15] with parents of children with neurodevelopmental conditions. PACT-F content includes 1) education about parent MH problems among parents of children with PFD, 2) interactive learning of FACT skills, including cognitive defusion, mindfulness, and value-based decision making, and 3) education about the importance of positive parent-child interactions at mealtime and how to apply PACT-F skills to their mealtime interactions with their child with PFD. Each session lasts 90 minutes and will be conducted remotely via Microsoft Teams.

Control. The content of the control intervention covers a range of nutrition and healthy lifestyle topics including USDA's *MyPlate.* The control condition has equivalent face-to-face time with the interventionists.

2.3 Drugs or Biologics: N/A

2.4 Medical Devices. N/A

2.5 Behavioral Intervention*:* Both the active and control conditions are behavioral interventions. See description above.

PARTICIPANT MANAGEMENT

7.0 Inclusion and Exclusion Criteria*

3.1 Eligibility Criteria:

Inclusion Criteria

- 1) Must be a parent aged 18+ (primary caregiver) of 2-6-year-old child with PFD
- 2) Child must be receiving outpatient PFD treatment at CMH
- 3) The parent must have a clinically significant elevation on at least one measure of parent MH (using established clinical cutoffs). Parents will be included regardless of whether the child has a new diagnosis or established diagnoses

Exclusion Criteria

- 1) Parent has significant cognitive impairments
- 2) Parent does not speak English
- Parent unable to obtain high speed internet at home

3.2 Equitable Selection*:* We are excluding non-English speaking participants because we are providing a behavioral intervention and do not have a translated version of the intervention available. In the future, we hope to translate this

intervention for non-English speaking patients but are unable to do this for the present study.

3.3 Vulnerable Populations: *Check any vulnerable populations <u>that are being targeted</u> for enrollment into the study: (Members of the following populations may not be included as participants in the research unless selected here.)*

☒ Children/Minors (under 7 years of age)
☐ Children/Minors (7-17 years of age)
☐ Neonates (infants less than 30 days old)
☐ Neonates of Uncertain Viability (infants less than 30 days old)
☐ Non-Viable Neonates (infants less than 30 days old)
☐ Wards of the State
☐ Fetuses
☐ Pregnant Women
☐ Adults with impaired decision-making capacity
☐ CM Employees
☐ CM Students/Residents/ Fellows
☐ Economically or Educationally Disadvantaged Persons
☐ Prisoners

- Children with pediatric feeding disorder will be enrolled, and adequate provisions will be made to solicit the informed consent of parents and/or guardians. Informed consent of children in this study would not be appropriate because children enrolled are under the age of 6 years and many of these children have developmental delays. Parents will be given sufficient time to decide if the study is right for them and will be given all the options during the consent conversation. Participants will be informed that they can withdraw from the research at any time.

8.0 Local Number of Participants

4.1

	Total consented (before meeting inclusion criteria)	**Group 1 (Active treatment)**	**Group 2 (Control)**	**Total (meet criteria and randomized)**
Enrollment Goal: *Number of participants to be enrolled = the number of participants to be consented or to be screened for chart reviews.*	80	20	10	30

Approximately 60% of subjects consented will not meet inclusion criteria after taking quantitative measures and so 80 subjects will need to be enrolled to meet 30 randomized subjects. If number of randomized subjects reaches 30 prior to 80 being enrolled, enrollment will cease.

9.0 Identification and Recruitment of Potential Participants*

4.2 Identification of Potential Participants:

How will participants be identified? (Check all that apply)

☒ Chart reviews

☒ By their treating physician who will then provide the study team's contact information to the potential participant/family

☒ By their treating physician who will obtain patient/family permission to share contact information with the study team

☐ Self-refer in response to IRB approved advertisements or websites

☐ Through Cerner or other CM sources (e.g. databases, billing records, pathology reports, admission logs, etc.) May involve access of records by individuals not involved in the patient's care.

☐ List of candidates provided through the Data Report Request Form

☐ Registry of individuals interested in research opportunities

☐ Past participant list

☐ Participants will roll-over from another research study: Study #

☐ Other:

4.3 Pre-Screening prior to HIPAA Authorization

Will any of the identification methods checked above involve access to Protected Health Information (PHI) prior to obtaining HIPAA Authorization?

☒ Yes

☐ No

- *If yes, a "Partial Waiver of HIPAA Authorization" is required. Be sure to make this selection in the "HIPAA & Confidentiality" section below and complete* ***Addendum E: Waiver/Alteration of HIPAA Authorization***

4.4 Recruitment of Potential Participants:

Parents will be screened at outpatient clinic visits to the CMH feeding clinic. Parents who agree to participate will then complete parent MH measures via REDCap on a tablet during the clinic visit. No PHI will be collected at this time. Potential subjects that meet inclusion criteria after completing the screening tool will be asked to participate in the study. At that time a ICF will be given to them and reviewed. All questions will be answered and adequate time will be given for a decision.

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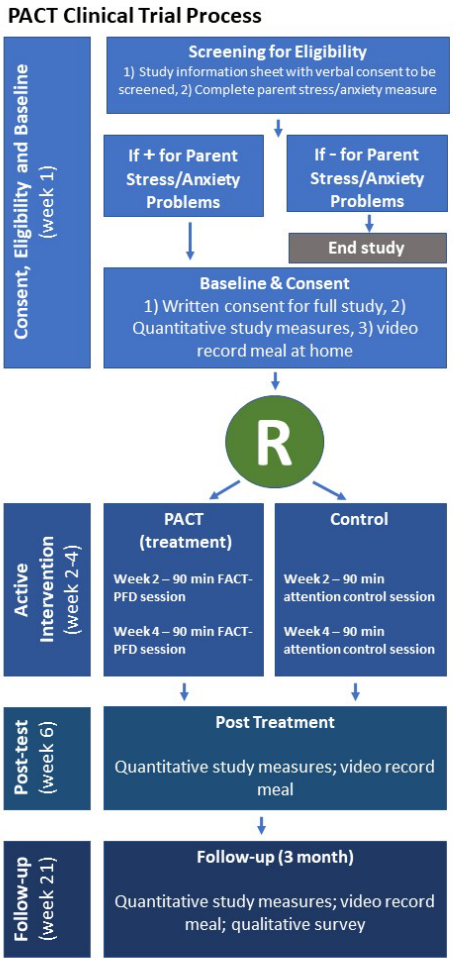
10.0 Procedures

Parents who meet inclusion criteria and sign consent will be randomized to either PACT-F or an attention control (control) condition using block randomization, such that an equal number of patients presenting for a new diagnosis and with an established diagnosis are randomized to each group. Participants will be blind to treatment condition (single blind study). See Figure 1 below for procedures. Intervention. Parents randomized to PACT-F will complete two 90-minute PACT-F sessions individually with a study interventionist, 2- weeks apart (see Table 2 for intervention content). Parents randomized to the control group will complete two 90-minute sessions individually with a study interventionist, 2-weeks apart (focused on nutrition education). The control intervention will be parallel to the PACT-F intervention in all ways, including interactive components and the face-to-face time with health professionals (interventionists). The control condition intervention has already been developed by Dr. Davis's research team and covers a range of nutrition and healthy lifestyle topics including USDA's *MyPlate.* Interventionists for both conditions will be individuals with at least master's degree training in mental health or a related field. The interventions will take place remotely via telehealth. The team has expertise in remote delivery of therapy in both clinical and research environments. Both arms of the intervention will be manualized and interventionists in both arms will be trained using didactics and role playing with the PI. Intervention fidelity will be monitored by audio recording all sessions. The PI (Dr. Bakula) will review video recordings each week and conduct weekly supervision.

Due to the nature of the study, the participants will be blinded to the group assignment during treatment. This is necessary as knowledge of whether they are in the treatment or control group may change behaviors of the participants. We will therefore not be able to give specific descriptions of the treatments in each group in the Informed consent form. Participants will be informed of their group assignment after they have completed the 3-month follow up and if they were in the control group be given the opportunity to participate in the treatment group. There is no difference in risk for either group.

Once the 3-month follow up is complete the subjects will be contacted and unblinded and control subjects will be offered the active treatment.

Figure 1



5.2 Blood and Other Specimen Collection:

N/A

11.0 Surveys and Psychometric Testing:

- Parent Mental Health (MH) Measures.
  - PHQ-9. A 9-item self-report measure of depressive symptoms. Scores of 10 or more indicate probable depression.
  - GAD-7. A 7-item self-report measure of anxious symptoms. Scores of 10 or more indicate probable anxiety.[87]

  - IES-R. A 22-item self-report measure of posttraumatic stress symptoms. Scores of 33 or more indicate clinically significant posttraumatic stress.
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- Exit survey: Parents will complete an exit survey at the 3 month visit via RedCap on their feelings about the study and offer a chance to give feedback on their experiences.

12.0 Follow-up

13.0 Genetic Analysis Information

5.1 N/A

14.0 Sharing of Results with Participants

5.2 A study summary of individual results will be offered to all subjects when they complete the study.

15.0 Risks to Participants*

5.3 This study is minimal risk, and the only foreseeable risk is the loss of confidentiality in the event of a data breach. Precautions have been taken to ensure data confidentiality, such as data storage in a secure REDCap database, with only trained/approved study staff having access to the data.

16.0 Potential Benefits*

5.4 Parents may find these sessions helpful in managing their own stress, as the protocol used has been shown to be effective in reducing parent distress in other pediatric populations. Additionally, the information shared by these subjects has the potential to help other families in the future.

17.0 Investigator Assessment of Risk/Benefits Ratio*

17.1 *Please provide an assessment of risk and benefits in the table below. Note, the IRB makes the final determination based upon responses in the two preceding sections.*

Select as applicable:	**Pediatric Risk Category:**	
☒	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
☐	Category 2	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants. (45 CFR §46.405 and 21 CFR §50.52)
☐	Category 3	Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition. (45 CFR §46.406 and 21 CFR §50.53)
☐	Category 4	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR §46.407 and 21 CFR §50.54)
Select if applicable:	**Adult Risk Category:**	
☒	Not Greater than Minimal Risk	
☐	Greater than Minimal Risk	

18.0 Payment, Reimbursement and Tangible Property provided to participants*

Is payment, reimbursement, or tangible property part of the study?

☒ Yes ☐ No *(If No, delete the following subsections)*

Payment to Participants: *If providing payment for participation (e.g. cash equivalent for participation, payment for time off work), select the form of payment:*

Study Activity	Payment
Screening measures	$ 5
Baseline forms	$30
Post-treatment measures	$ 40
3-month follow up measures	$ 50
Total	**$ 125**

☒ Gift card
☐ Prepaid Merchant Gift Card: (Merchant:_____)
☒ e-Gift card
☐ Other: _____

5.5 Reimbursement: N/A

5.6 Tangible Property: N/A

19.0 Compensation for Research-Related Injury

5.7 *N/A*

20.0 Economic Burden to Participants

6.1 N/A. Intervention sessions will be scheduled at times convenient to the family so they should not interfere with work schedules. Telehealth is being utilized to reduce burden and eliminate travel costs. No clinical fees associated with study procedures will be incurred for parents who take part in this clinical trial.

21.0 Parental Permission and Adult Consent Process*

21.1 *For screening purposes, we will give the parents an information sheet explaining that we are asking them to complete questionnaires to see if they meet criteria to participate in the main part of the study and will answer any questions they have. We are requesting a waiver of the documentation of permission/consent for this. The parent completing the questionnaires will be considered implied consent.*

If parent meets inclusion/exclusion they will then be presented the consent document and consent discussion for the main part of the study will happen. If they do not meet inclusion/exclusion they will be thanked for their participation.

Waiver of Documentation of Permission/Consent

Permission/Consent form provided but signature will **NOT** be obtained (e.g. verbal consent)
Must complete *Addendum A: Waiver of Documentation of Permission/Consent*

☒ **Waiver of written documentation of permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies: This only applies to the screening section of the study

☒ **Waiver of written documentation of consent of adult participants**

Study group(s) to which this method applies: This only applies to the screening section of the study

☐ **Waiver of written documentation of consent of participants turning 18**

21.2 Permission/Consent/Consent at 18 Discussion: N/A – no pediatric subjects will be turning 18 during their enrollment in the study. Children enrolled in the study are under the age of 6 and therefore are not close to their 18th birthday. Individual data will be deidentified once the study is complete. We will not access patient data after the child is 18 years of age.

21.3 Documentation of Permission/Consent/Consent at 18: *N/A*

21.4 Identification of participants turning 18: *N/A*

22.0 Assent of Pediatric Participants

22.1 Select the option(s) that apply to the study:

☐ **Assent of pediatric participants WILL BE SOUGHT following assessment of ability to assent.**

☒ **Obtaining assent of pediatric participants is NOT POSSIBLE due to:**

☒ *The capability of the participants (considering the ages, maturity, physical and/or psychological state) is so limited that they cannot reasonably be consulted.*

☐ *The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participants and is available only in the context of the research.*

☒ **Obtaining assent of pediatric participants is NOT PRACTICAL given the context of this study** (e.g., minimal risk, no direct contact with participants). **Must complete *Addendum B: Waiver/Alteration of Permission/Assent/Consent***

☐

22.2 Assessment of Ability to Assent: *N/A*

22.3 Assent Discussion: *N/A*

22.4 Documentation of Assent or Inability to Assent: *N/A*

23.0 HIPAA and Confidentiality

HIPAA regulations apply to this study if the data used or accessed relates to:

- The past, present or future physical or mental health or condition of an individual;
- The provision of health care to an individual; **OR**
- The payment for the provision of health care, **AND**

identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.

23.1 HIPAA Authorization

Select all applicable methods of HIPAA Authorization that apply to this study.

☒ Full Written HIPAA Authorization will be obtained (within the p/a/c form or standalone form)

☒ Partial Waiver of HIPAA Authorization (e.g. waiver for recruitment and pre-screening purposes only)
Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

a) *PHI accessed for pre-screening/recruitment will be name and medical record number .*

☐ Alteration of HIPAA Authorization (some but not all required elements of an Authorization are present, e.g. signature will not be obtained)
Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

a) *Describe which proposed elements to be altered.*

☐ Waiver of HIPAA Authorization (authorization will NOT be obtained)

☐ If Other, explain:

23.2 Specify the PHI for which **accessing ("viewing")** or **recording ("writing down")** is necessary for the purpose of this research:

To minimize risks, only the minimum necessary identifiable data should be accessed/viewed and/or recorded/written down.

	PHI	Accessed Only	Recorded
1.	Name/Initials	☐	☒
2.	All elements of date (except year) directly related to an individual (e.g. date of birth, admission date, discharge date, date of death)	☐	☒
3.	Medical record number	☒	☐
4.	Account number	☒	☐
5.	Health plan identification number	☐	☐
6.	Social Security Number	☐	☐
7.	Device identifiers and serial number	☐	☐
8.	Certificate/License number	☐	☐
9.	Telephone number	☐	☒
10.	Fax number	☐	☐
11.	Email addresses	☐	☒
12.	Web addresses (URLs); Internet IP addresses	☐	☐
13.	Street address, city, county, precinct, zip code or equivalent geographical codes	☐	☐

14. Full face photographic images and any comparable images (this includes use of video recordings via Teams)	☐	☐
15. Biometric identifiers, including finger and voice print (this includes recorded Teams audio)	☐	☐
16. Vehicle identifiers and serial numbers, including license plate number	☐	☐
17. Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g. student or employee ID number)	☐	☐
18. Elements of date, including year, for persons 90 years or older	☐	☐
19. Other:	☐	☐

23.3 Only necessary PHI will be recorded to ensure the participant's confidentiality is protected. All PHI and data recorded will be, aside from the hard copy of the consent form, stored in a secure drive that only study personnel have access.

23.4 A certificate of confidentiality has not been issued for this study.

24.0 Provisions to Protect the Privacy Interests of Participants*

24.1 Steps will be taken to protect the participant's privacy. The consent discussion will occur during a private meeting with the parent, and identifiable information will not be shared outside of the study team.

24.2 Efforts will be made to make the parents feel at ease with the research situation such as informing parents all procedures and questions are optional, and they can choose not to participate in any aspect of the research with no impact to their care in the RUBI clinic or at CM.

24.3 The research team will access the Interdisciplinary Feeding and Swallowing program schedule through the EMR and will screen patients' EMR data to determine if they are eligible for participation. This will be possible through a partial HIPAA waiver. Steps will be taken to ensure the participant's confidentiality is protected, and data will be stored in a secure drive that only study personnel have access.

25.0 Withdrawal of Participants*

7.2 There are no anticipated circumstances which subjects with be withdrawn from the research without their consent. Subjects may voluntarily withdraw by informing the study coordinators.

7.3 In the event of voluntary withdraw, data that has previously been collected with be retained, and future data collected during the RUBI Clinic will not be used for study purposes.

DATA MANAGEMENT

26.0 Data Collection*

8.1 We will collect questionnaire data from parents enrolled in the study. We will have parents video record a mealtimes with them and their child through a facilitated Microsoft Teams call. PHI accessed in the medical record will include patient Name, MRN, DOB, and Visit Date, phone number, address, and email address.

8.2 The PHI from the medical records will be abstracted by chart review. Questionnaires will be collected via REDCap survey. Mealtimes will recorded via a facilitated Microsoft Teams call. All data will be securely stored as outlined in the Data Management plan below.

8.3 **Sensitive Data:** We are not collecting sensitive data.

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27.0 Adverse Events and Unanticipated Problems*

9.1 **Monitoring:** Participating parents will be able to reach study staff at any time if they experience distress and will have ongoing contact with the RUBI team during their regular course of care. We will monitor parent responses to the depression screening measure (PHQ-9) as the responses are submitted. If a parent endorses clinically significant depression or endorses a positive response on the item asking about suicidal ideation, the PI (a licensed psychologist) will contact the parent to conduct a safety assessment and provide the parent with appropriate referrals for intervention as indicated (e.g., emergency room).
9.2 **Reporting:** We will follow Policy 5.11 Reportable Events of the CM Research Program Policies and Procedures in regard to reporting adverse events and other unanticipated problems to the CM IRB.

28.0 Statistical Analysis*

10.1 Data will be analyzed using SPSS. We will conduct descriptive statistics to evaluate the research endpoints of this study. We will

conduct correlations between demographic factors and endpoints to evaluate relationships that may influence these endpoints.

10.2 Quantitative Feasibility Analyses. Descriptive statistics (frequency counts, %s) will determine recruitment, retention, assessment, and intervention delivery success and will be compared to identified benchmarks of success (recruitment rate above 60%, and retention, assessment completion, and intervention completion rate above 80%). Factors that may impact success will be evaluated in relation to these outcomes using t- and chi-squared tests.

10.3 Qualitative Feasibility Analyses. Parent free text responses to feasibility questions will be imported into NVivo 12 software for coding. A coding tree will be developed a priori and periodically revised to include relevant inductive codes as emergent themes arise. Qualitative responses will then be double coded by PI and a graduate research assistant. Interrater reliability will be coded, with the goal of achieving 80% interrater reliability. PI mentor will provide direct supervision for data collection and analysis.

10.4 Proof of concept analyses. We use the Reliable Change Index (RCI; success defined as RCI > 1.96) to determine if there is a reliable signal of change for participants who are in the PACT (active treatment) group from baseline to post-treatment and follow-up. The RCI is a psychometric criterion used to evaluate whether change is significant at the level of the individual. An RCI will be calculated for each participant in the PACT (active treatment) group, using the following formula: RCI = observed difference score between measurements divided by the standard error of measurement of the difference. We will assess proof of concept for change in parent stress, parent anxiety, and parent behavior at meals (measured by the DINE).

10.5 Given the feasibility and proof-of-concept nature of this study, we are interested in seeing if these study procedures are feasible and if there are meaningful improvements (e.g., several points of improvement on rating scales) rather than statistical significance. The sample size was therefore selected to ensure that a large enough group of participants can be evaluated to be reflective of a heterogeneous group of parents.

10.6 Recruitment rate is the indicator of recruitment feasibility (# consented/total # eligible per week). We will track factors that may impact recruitment from both those who do and do not consent to participate (baseline characteristics, contact methods). Retention: The % of parents who are retained through the final measurement will be the indicator of retention success. Assessment: % missing data will be the indicator of assessment success. We will track factors that may impact assessment success (measure factors, baseline characteristics). Intervention delivery:

session completion rate will be the indicator of success. We will monitor factors that may impact intervention delivery (baseline characteristics, scheduling procedures).

29.0 Data and Specimen Management*

11.1 Data Management: Data will be collected and stored via REDcap. Data will include the endpoints in addition to data accessed from the medical record. Only study team members approved by the IRB will have access to the data. The data will be stored until the study is complete or until the youngest participant turns 18. Study coordinators will be responsible for the receipt of this data. Study team members will access these data through CM Institutional REDcap access.

11.2 Specimen Management: N/A

11.3 Biosafety Information

Will this study involve handling, transporting, or shipping any potentially hazardous biological material at/from a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

Will this study involve processing any potentially hazardous biological material at a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

If processing potentially hazardous biological materials, where will this work be conducted?

☐ Pediatric Clinical Research Unit (PCRU)

☐ Children's Mercy Research Institute Biorepository (CRIB)

☐ Children's Mercy Research Institute labs (mySafety ID#:_____)

☐ Other location

If "Other location," identify the location and mySafety ID# of the corresponding IBC protocol:

Location: _____

mySafety ID#: _____

30.0 Storing of Data and/or Banking of Specimens for Future Research

12.1 *If this study involves storing of data or banking of leftover specimens for future research, indicate how the use will be managed:*

☐ Contributing data and/or leftover specimens to an existing CM repository protocol (myIRB#_____)

☐ Contributing data and/or leftover specimens to an existing non-CM repository (Institution/Repository Name: _____)

☒ Not contributing to an existing repository for the management of data/specimens for future research use.

☐ Other:

31.0 Provisions to Monitor the Data to Ensure the Safety of Participants

N/A. This study does not involve more than Minimal Risk and therefore this section is not required.

13.1 *In addition to the Principal Investigator, which individual or group will be responsible for monitoring the data and safety for this study?*

☐ Sponsor or Sponsor Designee (including the Sponsor CRO)
☐ Data and Safety Monitoring Board (DSMB) or Data Safety Monitoring Committee (DSMC)
☐ Independent Monitor (s)
☐ Internal Committee at CM
☐ Other: _____

13.2 Data Safety Monitoring Plan: N/A

STUDY MANAGEMENT

32.0 Setting & Locations*

14.1 All visits will take place either during a MDC feeding clinic visit at Adelle Hall in the Gastroenterology outpatient clinics or via tele-video conferencing using Microsoft Teams with the participant at home. Measures completion will be done via redcap system.

14.2 As this study is focused on the mental health of caregivers, psychological resources will be readily available for caregivers if necessary. As there are no physical procedures being done a need for medical resources are not expected.

33.0 Multi-Site or Collaborative Research

Choose ALL relationship types that apply:

☐ ***Multi-Site Research:*** *Multiple sites will be engaged in this human research project. Sites will use the* ***same*** *protocol to conduct the* ***same*** *human research activities (except for minor variations due to local context considerations).*

☐ ***Collaborative Research:*** *Multiple sites will be engaged in this human research project. Sites will* ***not*** *be performing the* ***same*** *research activities. The Site submission will specify the specific research activities each site will perform.*

> ***REQUIRED****: Enter summary of site-specific activities that differ from the overall protocol:* *Click or tap here to enter text.*

☐ ***Student(s)*****:** Student(s) will help with this project and will be engaging their home institution.

☐ **Visiting *Resident(s) /* Visiting *Fellow(s)*:** Visiting Resident(s) / Visiting Fellow(s) will help with this project and will be engaging their home institution.

Is Children's Mercy (CM) acting as the single IRB of Record (sIRB)?

☐ ***No, each site is getting their own IRB approval.***

☐ **Yes, some or all sites will rely on the CM as the sIRB**.

- ***Reliance is required*** *for non-Exempt* ***NIH*** *or other* ***Federally Funded*** *research where:*
  - *The institution's employees or agents intervene or interact with human subjects for research purposes;*
  - *The institution's employees or agents obtain individually identifiable private information or identifiable biospecimens about human subjects for research purposes; or*

- *The institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.*

If CM is sIRB for another site, complete the chart for that site(s) (*Add a new row for each site relying on the CM IRB, delete chart if not acting as sIRB):*

Site Name	**Enrollment Goal for Site(s)** ***Choose One***	**Relying on CM IRB?**
Insert Site Name	☐ **Site Enrollment Goal:** *Insert #* ☐ **Site will not enroll**	☐ External Site will rely on the CM IRB as the IRB of Record using a reliance agreement. () ☐ **Not Applicable**. Site will **not** interact or intervene with human participants or their identifiable data / identifiable biospecimens. Site is also not a primary NIH or federal grant recipient.

34.0 International Research

15.1 *N/A*

Addendum A: Waiver of Documentation of Permission/Consent

*(*for screening only_

Regulatory Criteria: *To qualify for a waiver of documentation of parental permission or adult consent, the study must fit into at least one of the three scenarios below. Indicate which scenario(s) applies.*

☐ **The only record linking the participant and the research would be the permission/consent form and the principal risk is potential harm resulting from a breach of confidentiality.** Each parent/LAR or adult participant will be asked whether they want documentation linking the participant with the research, and the parent/LAR's or adult participant's wishes will govern.

OR

☒ **The research presents no more than minimal risk of harm to participants and involves no procedures for which written parental permission or adult consent is normally required outside of the research context.**

OR

☐ **The parent(s)/LAR or adult participants are members of a distinct cultural group or community in which signing forms is not the norm**, the research presents no more than minimal risk of harm to participants and an appropriate alternative mechanism for documenting that informed parental/LAR permission or adult consent was obtained will be provided. Describe the alternative mechanism provided:

Addendum B: Waiver/Alteration of Permission/Assent/Consent

What's the difference between a "waiver" and an "alteration" of parental permission, child assent, or adult consent?

- A "waiver" of parental permission, child assent, or adult consent is when **all 9 required elements of permission/consent are waived.** If the IRB approves a waiver then the study team does not need to obtain the parental permission or adult consent in order to include a participant in the study.

- An "alteration" of parental permission, child assent, or adult consent is when **one or more of the 9 required elements are waived** because they are not relevant to the research activity. If the IRB approves an alteration, then the study team must still obtain parental permission or adult consent in order to include a participant in the study, but certain elements may not be required in the form/discussion.

NOTE: *If requesting a waiver of parental/LAR permission because parental permission is not a reasonable requirement to protect the participants [e.g. research on neglected or abused children], contact irb@cmh.edu to discuss additional regulatory requirements.*

Regulatory Criteria: *To qualify for a waiver or alteration of parental permission or adult consent,* ***ALL*** *of the following must apply. Explain how the study meets each of the regulatory criteria below.*

Criteria	Explain how the study meets the criteria
The research involves no more than minimal risk to the participants	
The research could not practicably be carried out without the requested waiver/alteration (i.e., explain why the study could not be done if permission/assent/consent were required)	
If the research involves using identifiable private information or identifiable	

biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	
The waiver/alteration will not adversely affect the rights and welfare of the participants	
Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation	

Proposed Alteration (if applicable):

Select which required elements of permission are to be omitted.

☐ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

☐ A description of any reasonably foreseeable risks or discomforts to the participant;

☐ A description of any benefits to the participant or to others that may reasonably be expected from the research;

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

☐ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

☐ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

☐ An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant;

☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled; and

☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or

☐ A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Provide the rationale for omitting the item(s) selected:

Addendum E: Waiver/Alteration of HIPAA Authorization

What's the difference between a "waiver" and an "alteration" of HIPAA Authorization?

- A "waiver" of HIPAA Authorization is when **the requirement to obtain authorization is completely waived.** If the IRB approves a waiver then the study team does not need to obtain HIPAA Authorization in order to include a participant in the study.

- An "alteration" of HIPAA Authorization is when **one or more of the required elements of authorization are waived.** If the IRB approves an alteration then the study team must still obtain HIPAA Authorization in order to include a participant in the study, but certain elements may not be required in the form/discussion. The study team should still verify the identity of the participant as part of the process. For an online survey, for example, this could be accomplished by having the participant type in their name.

Regulatory Criteria: *To qualify for a waiver/alteration of HIPAA Authorization,* ***ALL*** *of the following must apply to a study. Explain how the study meets each of the regulatory criteria below.*

Criteria	*Explain how the study meets the criteria*
The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based upon the following: a. Plan to protect PHI from improper use and disclosure: b. Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: c. Assurance that PHI will not be reused or disclosed to any other person or entity:	A partial waiver of HIPAA authorization is being used only to identify potential research subjects. No PHI will be recorded in the research record. Name will be recorded in enrollment log and for payment purposes. The RedCap database with answers to the questionnaires will be de-identified. Any PHI will not be reused or disclosed to any other person or entity.

The research cannot practicably be conducted without the waiver/alteration, i.e. explain why a signature for HIPAA Authorization cannot be obtained.	It would not be practicable to get HIPAA authorization from potential study participants prior to determining if they even meet study criteria. It would cause PHI to be recorded that would not be recorded otherwise.
The research cannot practicably be conducted without access to and use of the PHI, i.e. explain why access to PHI is needed for this study.	We need access to PHI in order to identify potential subjects that nominally meet study criteria.