Feeling and Body Investigators for Pediatric Abdominal Pain (FBI)

NCT02075437

01/28/2019

DUHS IRB Application (Version 1.7)

General Information

***Please enter the full title of your protocol:**

The Duke Tummy Pain Study for Children

***Please enter the Short Title you would like to use to reference the study:**

Feelings/Body Investigators
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Add Study Organization(s):

List Study Organizations associated with this protocol:

Primary Dept?	Department Name
◉	**DUHS** - Duke Default Department

Assign key study personnel (KSP) access to the protocol

*** Please add a Principal Investigator for the study:**

(Note: Before this study application can be submitted, the PI MUST have completed CITI training)

Nancy Zucker

3.1 If applicable, please select the Key Study personnel: (Note: Before this study application can be submitted, all Key Personnel MUST have completed CITI training)
*** Denotes roles that are not recognized in OnCore. Please select an appropriate role that is recognized in all clinical research applications (iRIS, OnCore, eREG, etc.)**

A) Additional Investigators, Primary Study Coordinator (CRC), and the Primary Regulatory Coordinator (PRC):

Small, Brian
Primary Regulatory Coordinator

B) All Other Key Personnel

Curtis, Mikayla
Other*
Datta, Nandini
Graduate Student
Davenport, Clementina

Other*
Erwin, Savannah
Graduate Student
Farber, Madeline
Graduate Student
Ives, Lindsay
Graduate Student
Marsan, Samuel
Interviewer/Surveyor
Mauro, Christian
Sub-Investigator
Pendergast, Jane
Collaborator*
Rivera-Cancel, Alannah
Clinical Research Specialist/Study Assistant
Romer, Adrienne
Graduate Student
Savereide, Erik
Clinical Research Specialist/Study Assistant
Wagner, Henry
Analyst*
Zhang, Xiyuan
Other*

***Please add a Study Contact:**

Small, Brian
Zucker, Nancy

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g., The study contact(s) are typically the Principal Investigator, Study Coordinator, and Regulatory Coordinator.)

Oncore

Please select the Library for your Protocol:

This field is used in OnCore. Determines the Reference Lists, Forms, Protocol Annotations, Notifications, and Signoffs available for the protocol. Protocols that require reporting to the NCI (National Cancer Institute), must select the Oncology library.

- ○ Oncology
- ◉ Non-Oncology

Protocol Application Type

Select the type of protocol you are creating:

Please see additional criteria and information in the policy titled "Reliance on the IRB of Another Institution, Organization, or an Independent IRB" on the **IRB web site**.

- ◉ Regular Study Application - Most common. The IRB will determine if the study is eligible for expedited review or requires full board review upon submission.
- ○ Application for Exemption from IRB Review - Includes Exempt, Not Human Subject Research, & Not Research.
- ○ External IRB Application - Any study using an external IRB as the IRB-of-Record.

- ○ Trainee Research While Away from Duke - Research conducted by medical students overseen by the Office of Curriculum & other student/trainee research away from Duke.
- ○ Individual Patient Expanded Access, Including Emergency Use - Use of an investigational product under expanded access, including emergency use of an investigational drug or biologic or emergency use of an unapproved device.

Conflict of Interest

Do any of the participating study investigators or other key personnel (or their immediate family/significant other) have a financial or intellectual interest in, or are receiving compensation from, the sponsor or the drugs, devices or technologies used in this research?

○ Yes ◉ No

Are any key personnel an inventor of any of the drugs, devices or technologies used in this research?

○ Yes ◉ No

Do any key personnel have or anticipate (within the year) any financial relationships (e.g., consulting, speaking, advisory boards, patents, equity, options) that could be perceived to overlap or present a conflict of interest with the current research?

○ Yes ◉ No

Do any key personnel have a conflict of interest management plan (issued by the Duke University School of Medicine Research Integrity Office) with this company?

○ Yes ◉ No

Oversight Organization Selection

CRU (Clinical Research Unit) or Oversight Organization Selection:

Please select the CRU.

Psychiatry

The Clinical Research Unit that takes responsibility for this study.

- More information on CRUs can be found on the Duke Office of Clinical Research (DOCR) website, **http://docr.som.duke.edu**
- Questions concerning CRU selection should be directed to docr.help@dm.duke.edu.
- For questions about the Campus Oversight Organization, please visit **Campus Oversight Organization**.

List all Key Personnel on the study who are outside Duke:

- **Note:** You will also need to attach the documentation of Human Subjects Certification for each individual, if they have completed the certification somewhere other than Duke.
- **If outside key personnel will have access to Duke PHI, a data transfer agreement AND external site IRB approval (or IRB authorization agreement) will be needed.** See HRPP policy **Use of Research Data by Former Duke Students or Former Duke Faculty and Employees**
- In the panel below, "PHI" is Protected Health Information.

Entry 1

Name	Stephen W. Porges
Study Role	Data Analyst
Email Address	stephen_porges@med.unc.edu
Institution / Organization	UNC Chapel-Hill
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	○ Yes ◉ No

Entry 2

Name	Greg Lewis
Study Role	Data Analyst
Email Address	greg_lewis@med.unc.edu
Institution / Organization	UNC Chapel-Hill
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	○ Yes ◉ No

Entry 3

Name	Maria Isabel Davila Hernandez
Study Role	Data Analyst
Email Address	maria_davila@med.unc.edu
Institution / Organization	UNC Chapel-Hill
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	○ Yes ◉ No

Entry 4

Name	Helen L. Egger, M.D.
Study Role	Co-Investigator
Email Address	helen.egger@duke.edu
Institution / Organization	NYU & Duke

Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	○ Yes ◉ No

Entry 5

Name	Nancy Spencer
Study Role	External Investigator
Email Address	nancy.spencer509@gmail.com
Institution / Organization	None/Independent Contractor
Will he/she have access to Duke P.H.I.?	◉ Yes ○ No
Is he/she an unpaid volunteer at Duke on the study?	○ Yes ◉ No

Entry 6

Name	Kyra Citron
Study Role	Data Entry
Email Address	kec61@duke.edu
Institution / Organization	Duke University
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	◉ Yes ○ No

Entry 7

Name	Bruny Kenou
Study Role	Data Entry
Email Address	bvk5@duke.edu
Institution / Organization	Duke University
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	◉ Yes ○ No

Entry 8

Name	Ashley Kelly

Study Role	Data Entry
Email Address	ashley.kelley@duke.edu
Institution / Organization	Duke University
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	◉ Yes ○ No

Entry 9

Name	Tejaswi Siripurapu
Study Role	Volunteer
Email Address	siripurapu20t@ncssm.edu
Institution / Organization	North Carolina School of Science and Mathematics
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	◉ Yes ○ No

Indicate the Protocol source below:

The protocol source is the author of the protocol. If the protocol is a joint authorship between multiple sources, select the primary author.

An IRB fee may be assessed for all research that is supported by for-profit entities and requires full board review. For additional information, see the **IRB fees section of the IRB web site**

- ◉ PI initiated
- ○ Commercial / Industry (for-profit entity) initiated
- ○ Federal Government initiated
- ○ Cooperative Group Initiated
- ○ Foundation (non-profit group) initiated
- ○ Other

Sponsor and Funding Source

Add all funding sources for this study:

View Details	Sponsor Name	Sponsor Type	Contract Type:	Project Number	Award Number
⊟	Duke University	Institutional			

Sponsor Name:	Duke University
Sponsor Type:	Institutional
Sponsor Role:	
Project Period:	From: to:

Is Institution the Primary Grant Holder:	No
if No, then who is the Primary Grantee?	
Contract Type:	
Project Number:	
Award Number:	
Grant Title:	
PI Name: (If PI is not the same as identified on the study.)	
Explain Any Significant Discrepancy:	

Is this a federally funded study?

○ Yes ◉ No

Does this study have any of the following?

- Industry sponsored protocol
- Industry funded Duke protocol
- Industry funded sub-contract from another institution
- Industry provided drug/device/biologic
- SBIR/STTR funded protocol

○ Yes ◉ No

As part of this study, will any samples or PHI be transferred to/from Duke to/from anyone other than the Sponsor, a Sponsor subcontractor, or a Funding Source?

○ Yes ◉ No

Is the Department of Defense (DOD) a funding source?

○ Yes ◉ No

Have you successfully synced your protocol to OnCore by clicking the 'Sync Data Over API' button at the top of this page?

Please verify that the protocol has been created in OnCore before submitting this application for PI Signoff.

◉ Yes, I synced my protocol to OnCore and verified it was successfully sent by logging into OnCore.
○ I may have forgotten! I'll click it again right now, just to be sure, and verify it was successfully sent by logging into OnCore.

Mobile Devices and Software

Does this study involve the use of a software or a mobile application?

○ Yes ◉ No

List all software, including third party (non-Duke) and mobile apps, that will be utilized for ascertainment, recruitment, or conduct of the research/project: (eg, MaestroCare, DEDUCE):

Multi-site Research

Is this a multi-site study?

○ Yes ◉ No

Complete for each site if Duke is the Primary grant awardee or coordinating center:

Entry 1

Site Name:	
City:	
State/Province:	
Country:	
	Site Contact Information
Primary Contact Name:	
Primary Contact Phone:	
Primary Contact Email:	
	Site Details
Does the site have an IRB?	○ Yes ○ No
Site IRB approval expiration date:	
If date not provided, explanation of why:	
Has the site granted permission for the research to be conducted?	○ Yes ○ No
Does the site plan to rely on the DUHS IRB for review?	○ Yes ○ No
What is the status of the study at this site?	○ Open ○ Closed
Site approval letters or site personnel lists:	Attach site approval letters, site closure letterS (if applicable), or site personnel lists in the Initial Submission Packet.

Research Abstract

Please type your Research Abstract here:

The Research Abstract should summarize the main points of your study in one paragraph. The following guidelines may help you:

1. Purpose and objective (1-2 sentences)
2. Study activities and population group (2-4 sentences)
3. Data analysis and risk/safety issues (1-2 sentences)

This proposal, *Feelings and Body Investigators (FBI): Interoceptive Exposure for Child Abdominal Pain* is in response to PA-11-177, Translational Research for the Development of Novel Interventions for Mental Disorders (R21/R33). We describe the development and pilot-testing of an acceptance-based behavioral treatment for young children (5-8 years old) with functional abdominal pain (FAP; R21, n=26, R33, n=100). FAP is one of the most frequent somatic syndromes in young children, causes significant impairment, and is predictive of psychiatric and pain disorders. No treatments exist for very young children with FAP. Early intervention may not only improve pain and decrease impairment, but also may have broad implications for the prevention of future psychiatric and pain disorders and for improvement in the emergence of adaptive self-regulatory capacities (e.g. emotion regulation). We propose that FAP results from the influence of pain on neurodevelopment of the gut-brain axis combined with maladaptive interactions with the social environment that inadvertently increase somatic fear. We address these vulnerabilities by 1) linking intervention strategies to unique patterns of neural circuit maturation associated with early visceral pain on the gut-brain axis, 2) adapting acceptance-based behavioral strategies used to address psychopathology in older children to younger children, and 3) incorporating caregivers as role models and facilitators. For the R21, we iteratively develop the intervention, training children to be "FBI agents- Feeling and Body Investigators," an acceptance-based interoceptive exposure intervention. Interoceptive exposure involves the deliberate manipulation of somatic signals to reduce somatic fear and enhance functioning (e.g. getting the gut to have more butterflies). Child/caregiver dyads: 1) gather body clues (*Learn*), 2) investigate (*Experience*: perform interoceptive mystery missions to explore a body sensation), 3) organize body clues (*Contextualize*: recall other contexts that evoke similar sensations, e.g. emotions), and 4) go on increasingly daring missions (*Ch allenge*: decrease avoidance and safety behaviors, provoke stronger sensations while performing activities). Ten sessions are done in clinic (n=8) and home via web-camera (n=2) to facilitate generalization. The intervention is theoretically grounded in attachment research and developmental neuroscience, with a focus on how children learn to interpret the meaning of visceral signals (e.g. is this gut sensation the butterflies of anxiety or the pangs of hunger?). We use epidemiological methods to screen all eligible children via primary care practices to examine the potential impact of our intervention. In the R33 phase, we randomize to FBI or parent education to examine clinical and statistical change. The control parent education condition provides an added deliverable by providing materials about FAP for use in primary care. If we are successful, young children with FAP will experience changes in the viscera as fun and fascinating with broad implications for the emergence of emotion awareness and regulation, improvement in function, and prevention of disease.

Research Summary

State your primary study objectives

Developmental (R21) Phase. We will develop and refine the FBI intervention in 26 child-caregiver dyads.

A1. Create a developmentally sensitive interoceptive exposure treatment for young children with FAP.

A2. Assess the initial feasibility of FBI.

Hypotheses: HA2$_a$, ≥ 80% of participants enrolled in FBI will complete treatment, **HA2$_b$**, ≥ 80% of participants will complete home-based practice assignments.

A3. Assess the clinical significance of FBI post-treatment.

Hypothesis : HA3, Children will endorse weekly pain and distress ratings of minimal to none (≤ 2).

Pilot-Test (R33) Phase. We will randomize 100 children with FAP to FBI or an active control (parent education with standard medical care**).**

B1. Determine feasibility of the intervention.

Hypotheses: HB1$_a$, ≥ 80% of participants will complete treatment and **HB1$_b$**, homework.

B2. Determine the acceptability of the intervention.

Hypotheses: HB2$_a$, ≥ 80% of parents and children in FBI will endorse Very Much/Extreme positive ratings on treatment credibility and **HB2$_b$**, satisfaction.

B3. Assess clinically meaningful change in the intervention group compared to control.

Hypotheses: HB3$_a$, Compared to control, children in FBI will endorse: fewer episodes of abdominal pain (Faces Scale), **HB3$_b$**, greater reductions in impairment (Children's Global Assessment Scale)

State your secondary study objectives

Exploratory: greater improvements in emotion awareness and regulation via increased abilities to **HB3$_c$**, discriminate emotion from pain (via daily diaries) and **HB3$_d$**, regulate emotional experience (laboratory mood induction task).

Please select your research summary form:

Standard Research Summary Template

This is the regular (generic) research summary template which is required for all regular applications (unless your protocol fits under the other research summary templates in this category). Use of these instructions is helpful for ensuring that the research summary contains all necessary elements.

Standard Research Summary

Purpose of the Study

- Objectives & hypotheses to be tested

Developmental (R21) Phase. We will develop and refine the FBI intervention in 26 child-caregiver dyads.

A1. Create a developmentally sensitive interoceptive exposure treatment for young children with FAP.

A2. Assess the initial feasibility of FBI.

Hypotheses: HA2$_a$, ≥ 80% of participants enrolled in FBI will complete treatment, **HA2$_b$**, ≥ 80% of participants will complete home-based practice assignments.

A3. Assess the clinical significance of FBI post-treatment.

Hypothesis : HA3, Children will endorse weekly pain and distress ratings of minimal to none (≤ 2).

Pilot-Test (R33) Phase. We will randomize 100 children with FAP to FBI or an active control (parent education with standard medical care**).**

B1. Determine feasibility of the intervention.

Hypotheses: HB1$_a$, ≥ 80% of participants will complete treatment and **HB1$_b$**, homework.

B2. Determine the acceptability of the intervention.

Hypotheses: HB2$_a$, ≥ 80% of parents and children in FBI will endorse Very Much/Extreme positive ratings on treatment credibility and **HB2$_b$**, satisfaction.

B3. Assess clinically meaningful change in the intervention group compared to control.

Hypotheses: HB3$_a$, Compared to control, children in FBI will endorse: fewer episodes of abdominal pain (Faces Scale), **HB3$_b$**, greater reductions in impairment (Children's Global Assessment Scale), and, **Exploratory:** greater improvements in emotion awareness and regulation via increased abilities to **HB3$_c$**, discriminate emotion from pain (via daily diaries) and **HB3$_d$**, regulate emotional experience (laboratory mood induction task).

Background & Significance

- Should support the scientific aims of the research

The Duke Tummy Pain (DTP) Study Research Summary

R-21 Phase

The Feelings and Body Investigators (FBI): Interoceptive Exposure for Child Abdominal Pain proposes to develop (R21) an acceptance-based behavioral treatment intervention for children 5 through 9 years old with impairing functional abdominal pain. Functional abdominal pain (FAP) is a frequent somatic complaint in young children (approximately 10% of those presenting to primary care) and is responsible for distress in the afflicted child and the family; unnecessary health care utilization and cost; and interference with schooling. Further, FAP is predictive of future pain disorders, psychiatric disorders, and impairment. Despite this prevalent and significant burden, there are currently no accepted successful treatments for FAP in young children.

The objective of this proposal is to develop an intervention for FAP based on fundamental research on aberrant neurodevelopment of the gut-brain axis and subsequent modification by the social environment. In brief, this work suggests that FAP results from the influence of pain on the neurodevelopment of the gut-brain axis. The gut-brain axis maintains the body's homeostasis, encompassing capacities to sense changes in the viscera and respond adaptively (e.g., responding to gut pangs of hunger). Healthy maturation of the gut-brain axis is crucial for the emergence of weight and emotion regulation. Further, the interpretation of visceral signals has a developmental course, as children learn how to identify, label, and describe body sensations; e.g., whether gut sensations are butterflies of anxiety or gut pain. FAP represents a disruption of this normal developmental course. FAP may also be exacerbated by environmental influences (e.g., extensive medical diagnostic testing) that increase parents' health anxiety and their children's fear and distrust of their bodies. We propose to intervene directly early in development on these aberrations in gut-brain maturation by training eligible child-caregiver dyads to be feelings and body (FBI) investigators using interoceptive exposure (the manipulation of visceral sensation) to explore a "body mystery" in a playful, investigative context designed to increase curiosity about body function. Sessions are conducted in clinic and home (via web-camera) to facilitate generalization.

Because of limited sample size and the iterative nature of intervention development, criteria for success at the R21 Phase are based primarily on clinical rather than statistical criteria. We have established goals for compliance, completion, and reduction in physical and psychological distress aimed at establishing the feasibility and efficacy of the intervention. We carefully considered statistical constraints of pilot investigations by framing outcomes based on clinical but not statistical significance.

There are no known physical risks to the child or parent associated with this proposed study.
There are minimal risks such as feeling uncomfortable answering questions.

Design & Procedures

- Describe the study, providing detail regarding the study intervention (drug, device, physical procedures, manipulation of the subject or the subject's environment, etc.). Discuss justifications for placebo control, discontinuation or delay of standard therapies, and washout periods if applicable. Identify procedures, tests and interventions performed exclusively for research purposes or more frequently than standard of care. Include alternative therapies, concurrent therapies discontinued per protocol, risk benefit ratio, and use of tissue/specimens. Discuss monitoring during washout periods if applicable. Include brief description of follow-up, if any.

Treatment Procedures/Quality Control for R21

Treatment Procedures: Treatment sessions will be conducted in the Duke Young Child Laboratory (see below). For home-based sessions, we use web-cameras so the participants can practice new skills at home to facilitate generalization. All families will be given a web-camera, if needed, for this purpose. As with all procedures, children lead the sessions (the "FBI missions") both to maximize their engagement and minimize their fears of body-focused exposures. While part of the treatment is gently nudging children to do things that produce a somatic sensation, yet it is critical that children feel safe and thus they can terminate a session whenever they wish. Our typical approach to such a request is to first attempt to titrate the exposure down to a level that is acceptable for the children until they are excited about the mission. In the event of continued refusal, we use the session to hone our "observational skills" or go into "investigative mode" figuring out why today is such a rough day. Thus, sessions are always productive – no matter what the emotional state of the child, but yet always sensitive to the needs of the child.

Assessment Procedures

Four separate assessment types occur throughout the study:

a) 7 days of daily pain diaries (approximately 15 minutes per day)

b) Parent and child-completed surveys (approximately 1 hour)
c) Parent interview (approximately 3 hours)
d) Laboratory mood induction task (approximately 1 hour)

All laboratory assessments (and some treatment sessions) will be conducted in our Duke Young Child Laboratory in the Center for Developmental Epidemiology, located on bus lines including free public bus lines with free parking and available childcare. The laboratory consists of a cheerful playroom where children can use toys and a comfortable interviewing room (adjacent to playroom) where parents will be interviewed (c) and children will complete the laboratory mood induction task (d). Parents will be able to use seating in the playroom during the mood induction task to complete the surveys (b).

The daily pain diaries (a) will be given to participants to fill out where ever works best for the participants. They will be given these three daily surveys to fill out, within a paper flip booklet which the subject will turn in to the researchers after the completing the Daily Pain Diaries.
We also send out a short questionnaire to our subject's teachers at two time points (which we are currently getting permission to do within our main study consent form that the parent fills out and signs, along with giving us the teachers name, school, address, e-mail address, and phone number). First we plan to contact the subject's teacher via e-mail to see if they would be willing to fill out these questionnaires, and if they e-mail us back, letting us know that they would like to participate, we will send the teacher a questionnaire link, via Duke Qualtrics, prior to the subject starting their investigational treatment sessions. We would then e-mail the teacher a second time, after the subject has completed all 10 of the treatment sessions, to see if they would be willing to again fill out these questions via a Duke Qualtrics link.

Assessment Measures:
Feasibility: Hypotheses $A.H2_a$, $A.H2_b$/$B.H1_a$, $B.H1_b$:
We will keep a continuous measure of session attendance with missed sessions that are rescheduled within a two-week window (to account for vacations, etc.). Homework practice is recorded by therapists at every session (number of practice sessions completed regardless of degree of completion) and quality of homework (none, attempt, completed) to provide a continuous measure of treatment feasibility.

Clinical Significance: Hypotheses $A.H3_a$ /$B.H3_a$, $B.H3_b$, $B.H3_c$, $B.H3_d$
Treatment efficacy is assessed along dimensions of: a) physical pain, b) impairment, and c) emotion-regulation (exploratory).

Pain: Children and their caregivers will be trained to complete pain ratings using a Daily Pain Diary which contains a Pain Thermometer to rate pain experienced and the Self-Assessment Manikin (SAM) scale to rate emotional experience. Caregivers are trained to use the child's verbal reports, facial expressions, and behaviors to make these ratings. Children make their ratings twice daily: in the morning and before dinner. Parents rate their child's pain three times daily: in the morning, before dinner, and at the end of the day. The end of day survey contains additional questions asking about the child's overall pain experience throughout the entire day, as well as their distress and mood. These ratings are completed for one week prior to treatment and one week post-treatment, on a daily basis. Pain ratings are collected during 2 of the 10 weeks of treatment.
Impairment: Change in function will be assessed by diagnostic interviews and global ratings of clinical and functional change by reviewers blind to the randomization on the basis of these interviews, functional status as reported in pain/emotion diaries, and medical chart review of frequency of visits and physician contacts.
Diagnostic Interviews: Dr. Helen Egger is the leading author of the Preschool Age Psychiatric Assessment (PAPA), one of the most widely used and reliable semi-structured interviews for diagnosis of young child psychopathology. The caregiver reports on his or her child's family context, psychiatric diagnosis, self-regulatory abilities including sensitivity to sensation, developmental history, and impairment. Numerous studies have established its predictive validity and sensitivity to change with intervention. Impairment is assessed across multiple domains as well as the perceived cause of impairment (e.g. due to physical symptoms). To shorten administration, modules chosen are based on frequency of somatic symptoms and include ADHD, somatization, social phobia, separation anxiety, generalized anxiety, and depression.
Functioning ratings in daily pain diaries – Parents are asked to provide an assessment of their child's functioning three times per day. In the morning (beginning of day) and afternoon (before dinner), they rate their child's ability to pay attention and have fun whilst experiencing tummy pain. At the end of the day, they provide a detailed report of their child's physical and emotional functioning over the course of the day.
Global Ratings: Clinical Response - At pre and post-assessment, clinical status and improvement will be rated by blind raters on the eight-point Clinical Global Impression Scale Improvement. Participants who are rated as clinically improved or much improved in the area of physical symptoms will be considered treatment responders.
Global Ratings: Functioning - Global functioning will be rated by a rater blind to treatment status using the Children's Global Assessment Scale, a 100-point scale with 1 being most impaired and 100 being

least impaired. A score of 41–50 indicates a moderate degree of interference in functioning in most social areas or severe impairment of functioning in one area, whereas a score of 61–70 indicates generally functioning well with some difficulty in a single area. Scores of 70 or above will be considered responders.

Emotion Regulation: Emotion regulation is measured at pre- and post-treatment with our mood induction paradigm and child-reported emotional valence ratings in the daily pain diaries.

Mood induction laboratory paradigm - We employ a standardized mood induction paradigm for young children (viewing film clips). Additionally, we have children self-report on their emotions, pain, and hunger level, as well as changes in body sensation (movement of their heart and gut), throughout the task. Figure 4 provides a graphical representation of the mood induction task. To better assess the subject's physiological state while watching these mood inducing video clips, subjects will be hooked up to a BioPac machine which will collect the following physiological data: EEG, ECG, Galvanic Skin Response, and Respiration. The film clips include exciting clips,, sad clips, disgusting clips, fearful clips, and happy clips. If children have successfully learned to discriminate and regulate emotional experiences, they should 1) complete the lab task despite increased emotion, 2) change ratings of body sensation and emotion with each clip, but not pain

Child-reported emotional valence - We have children use the SAM scale in their daily pain diaries to assess their daily emotional state. By giving daily ratings of their emotional state, their pain state, and combining these with parent reports of the same, we can examine increasing segregation of ratings of pain from those of emotional experience.

R-33 Phase

As of February 2016, we have completed the R-21 phase of The Feeling and Body Investigators (FBI) Study (N=26) and have received approval to continue into the R-33 phase of the study. We are currently in the process of analyzing the data collected during the R-21 phase of the study, updating materials based on subject feedback, and preparing to begin recruitment of our next 100 subjects (N=100).

The R-33 phase, called The Duke Tummy Pain (DTP) Study, will differ from the R-21 phase in that we will be comparing our Investigational Treatment (Feeling and Body Investigator Treatment, or FBI) to a control treatment (Caregivers in Action Treatment, or CIA). Recruitment, eligibility criteria, and assessment strategies will stay the same as they were in the R-21 phase. Subjects recruited into the R-33 phase will be randomized to either the experimental treatment (FBI) or the control treatment (CIA), but both groups will receive the same number of treatment sessions (10), with 8 sessions conducted in our lab space and 2 sessions conducted via Skype.

The R33 period will repeat the goals of the R21 period using an improved intervention, a large sample to discern statistical and clinical significance, and a randomized design with a parent-psychoeducation comparison condition. Endpoints include quantification of whether this intervention can have broad impact: using primary care practices to screen and subsequently treat abdominal pain early in the life and disorder cycle.

Those who receive the FBI Investigational Treatment will still be trained using an improved version of the FBI R-21's interoceptive exposure (the manipulation of visceral sensation) to explore "body mysteries" in a playful, investigative context, designed to increase curiosity about body functions. The CIA (treatment as usual) focuses more on the parent, who will receive a psychoeducation comparison condition. Parents will receive educational handouts, similar to what they would receive from a Pediatricians office, and the therapist will review these materials with the parent, while the child is playing in the room.

As of November 2016, Dr. Helen Egger (a Co-PI on this study) has taken a position at NYU and will no longer be working with subject's PHI for this study. Helen will now be moved to our "Outside Duke Key Personnel" and is still involved with Duke, but as an adjunct professor.

Lastly, as of January of 2018 we plan to add a small group of 10-year-old children, N=10, as a pilot, to test our investigational therapy on an older age group.

April 2018: We have been approved and funded by the NIMH to include a diversity supplement under the FBI parent study. Through this supplement, we will be conducting a series of focus groups and interviews with Hispanic participants. If the goals of this project are reached, the deliverables from this project will include a novel intervention for young children (5-9 years old) with FAP which is tailored to needs of families of Hispanic origin. Subjects may only speak Spanish. The focus groups with be translated into Spanish. Consent forms have been translated into Spanish.

May 2019: To capture additional data for the diversity supplement, we will recruit parents who would be eligible to participate in the focus groups/interviews to complete an online Qualtrics survey instead of coming in-person to participate in a focus group or interview. Data collected from these participants will help inform the development of the novel intervention tailored to families of Hispanic origin.

Assignment to Study Group

For the R33 caregiver-child dyads will be randomized into one of two potential treatment groups: 1) Feeling and Body Investigators (FBI)- A child focused treatment, or 2) Caregivers In Action (CIA)- a parent focused treatment. Participants who refuse the study at the baseline encounter will also be entered into the tracking database to track characteristics of refusals.

Treatment Procedures/Quality Control for R-33
Treatment Procedures: Treatment sessions will be conducted either in the Duke Young Child Laboratory (see below) or in the Duke Center for Eating Disorders at Lakeview East. For home-based sessions, we use web-cameras so the participants can practice new skills at home to facilitate generalization. All families will be given a web-camera, if needed, for this purpose.
Those Assigned to FBI: Children will lead the sessions (the "FBI missions") both to maximize their engagement and minimize their fears of body-focused exposures. While part of the treatment is gently nudging children to do things that produce a somatic sensation, it is critical that children feel safe and thus they can terminate a session whenever they wish. Our typical approach to such a request is to first attempt to titrate the exposure down to a level that is acceptable for the children until they are excited about the mission. In the event of continued refusal, we use the session to hone our "observational skills" or go into "investigative mode": figuring out why today is such a rough day. Thus, sessions are always productive no matter what the emotional state of the child.
Those Assigned to CIA: These sessions will be focused on the psychoeducation of the parent, but the child will be in the room playing while the therapist is reviewing the educational materials with the parent. There will be a 10-lesson educational curriculum designed to educate caregivers about the management of their child with FAP. To create the curriculum for CIA, we reviewed patient handouts for exemplary pediatric gastrointestinal programs, professional healthcare organizations, and companies that supply the patient handouts incorporated into electronic medical record systems (e.g. Maestro). Following the review of these materials, we extracted the primary themes and lessons and organized them into a session-by-session curricula.

Assessment Procedures
**The same as the R-21 Phase, except for adding a 6 month follow up battery of questionnaires which will be sent to the parent via an e-mail link using Duke Qualtrics. These questionnaires will be the same as the questionnaires that caregivers fill out during the Lab 1 and Lab 2 portion of this study.

Assessment Measures:
Feasibility: Hypotheses $A.H2_a$, $A.H2_b$/$B.H1_a$, $B.H1_b$:
We will keep a continuous measure of session attendance with missed sessions that are rescheduled within a two-week window (to account for vacations, etc.) counted (range: 0-10). Homework practice is recorded by therapists at every session and rated by two independent blind raters on frequency (number of practice sessions completed regardless of degree of completion) and quality of homework (none, attempt, completed) to provide a continuous measure of treatment feasibility.

Clinical Significance: Hypotheses $A.H3_a$ /$B.H3_a$, $B.H3_b$, $B.H3_c$, $B.H3_d$
Treatment efficacy is assessed along dimensions of: a) physical pain, b) impairment, and c) emotion-regulation (exploratory).
All assessments will be the same as in the R-21 Phase

Selection of Subjects

- List inclusion/exclusion criteria and how subjects will be identified.

The primary care clinic where we recruited during the R-21 sees both privately insured and Medicaid children. The staff saw 1798 children between the ages of 5 and 9 years old in a previous study conducted at this clinic, The Preschool Anxiety Study. Based on our preschool cohort data (n=918) drawn from this primary care clinic, we expect 1) 8% to meet study criteria or 144 children. Assuming that 20% refuse to screen (approximately 30), we plan to screen 174 children. For the R33, we need to recruit 140 individuals to enroll 100 subjects; it will take 70 weeks to recruit this number (1.3 years). To get our N of 100 we plan to "consent to screen" close to 2,000 potential subjects. Having found that we had recruited most of the eligible subjects from the Picket Road Pediatric Clinic during the R-21 phase, we began recruiting from Duke's Southpoint Pediatric Clinic as well in late 2015. For the R-33 phase we plan to recruit from Duke's Southpoint Clinic, Durham Pediatrics, and potentially at Picket Road Pediatric Clinic once additional potential subjects have aged in. Further, based on our cohort data, we expect roughly equal numbers of males, females, ages, and those with a psychiatric disorder. We also found that the racial distribution of abdominal pain is roughly equivalent to the racial

and ethnic distribution of the Raleigh/Durham metropolitan region (45% Caucasian, 45% African-American, and 10% other underrepresented minorities). Thus, we are able to recruit a representative sample and make the intervention available to all who would benefit.

Subject Recruitment and Compensation

- Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate.

Recruitment Sampling Frame: The primary care clinic where we will recruit sees both privately insured and Medicaid children. The staff saw 1798 children between the ages of 5 and 9 years old in a previous study conducted at this clinic, The Preschool Anxiety Study. Based on our preschool cohort data (n=918) drawn from this primary care clinic, we expect 1) 8% to meet study criteria or 144 children. Assuming that 20% refuse to screen (approximately 30), we plan to screen 174 children. We need to recruit 26 individuals for phase 1 and phase 2 of the R21 and it will take us 18 weeks. Further, based on our cohort data, we expect roughly equal numbers of males, females, ages, and those with a psychiatric disorder. We also found that the racial distribution of abdominal pain is roughly equivalent to the racial and ethnic distribution of the Raleigh/Durham metropolitan region (45% Caucasian, 45% African-American, and 10% other underrepresented minorities). Thus, we are able to recruit a representative sample and make the intervention available to all who would benefit.

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Compensation for FBI Study Participants: The parent and child will be compensated up to $310 for their participation in the study. The parent will receive $5 a day for each day that they complete all 3 of the Daily Pain Diaries, up to $35 for the 1st week of Daily Pain Diaries (pre-treatment) and up to another $35 for the 2nd week of Daily Pain Diaries (post treatment). The parent will also receive $40 for the first mood induction laboratory assessment, and $100 for the second mood induction laboratory assessment. The parent will receive $35 for each of the parent-interviews (ePAPAs) that they complete (one pre-treatment and one post-treatment) and finally, they will receive a $30 gift card for completing the 6 month follow-up questionnaires. Children will receive a prize at the end of each assessment. No monetary compensation will be provided for the 10 intervention sessions, but children will be given an assortment of toys at the end of each in-person session.

Compensation for FBI Study Participants: **The same as the R-21 Phase except, the parent will receive a $30 Amazon gift card for completing a final 6 month follow-up survey.**

Compensation for Diversity Supplement Participants:
Both parent and child that participate in this study will be receiving compensation. Upon completion of the study parents will receive a $55 pre-loaded ClinCard. Upon the child's completion of a focus group /interview session they will receive a small toy. Parents who complete the online Qualtrics survey will be sent a $15 Amazon giftcard upon completion.

Consent Process

- Complete the consent section in the iRIS Submission Form.

Subject's Capacity to Give Legally Effective Consent

- If subjects who do not have the capacity to give legally effective consent are included, describe how diminished capacity will be assessed. Will a periodic reassessment occur? If so, when? Will the subject be consented if the decisional capacity improves?

Not applicable. Only parents with the capacity to give legal consent will be recruited.

Study Interventions

- If not already presented in #4 above, describe study-related treatment or use of an investigational drug or biologic (with dosages), or device, or use of another form of intervention (i.e., either physical procedures or manipulation of the subject or the subject's environment) for research purposes.

See above.

Risk/Benefit Assessment

- Include a thorough description of how risks and discomforts will be minimized (per 45 CFR 46.111(a) (1 and 2)). Consider physical, psychological, legal, economic and social risks as applicable. If vulnerable populations are to be included (such as children, pregnant women, prisoners or cognitively impaired adults), what special precautions will be used to minimize risks to these subjects? Also identify what available alternatives the person has if he/she chooses not to participate in the study. Describe the possible benefits to the subject. What is the importance of the knowledge expected to result from the research?

B.1) Protection Against Physical Risk

Monitoring and Management of Severe GI Pain. **It is critical that we have stringent guidelines for the appropriate management of varying pain levels in children with FAP to guide therapists in the implementation and dissemination of this intervention. The careful development of these guidelines will be an important deliverable from this project.** To develop these guidelines we 1) recruit from primary care to ensure children are under the care of a primary care physician; 2) we carefully abstract from medical records throughout the study the medical interventions proscribed and number of physician contacts initiated by study participants, and 3) we continually monitor pain from both the parent's perspective of the child and the child's perspective across study arms. This information is shared in weekly case consultation meetings attended by Dr. Zucker, a child psychologist and PI, relevant therapists, and when needed Dr. Gary Maslow. The level of monitoring and supervision will be the same across treatment arm. In the experimental arm, our goal is to develop behavioral guidelines to help children and caregivers manage abdominal pain. In the intervention, we teach children to quantify experience (including pain), the context in which these experiences occur, and the result of the actions taken we hope to build mastery in children with medical comorbidity so they can learn when it is appropriate to seek help, avoid activities, or gently nudge themselves to participate. Combined, these sources of data will be used to create guidelines for therapists managing abdominal pain from a psychological perspective to ensure the safety of their patients.

B.2a) Protection Against Psychological Risks: Recruitment Site (informed consent and screening)

Informed consent. All the data will be collected under proposals approved by the IRB of Duke University Medical Center. Brief consent will be obtained in the clinic to administer the short screening items. Informed consent will be obtained from the parent by the interviewer on the day of the baseline

assessment. Separate consents are given for the interview and for having the assessments and treatment sessions recorded for coding and quality control. Participants can sign any or all of these separate consents. They will be informed that they can refuse to answer any questions they choose, and can have the tape recorder/video recorders turned off at any time.

Psychological issues that arise during screening. The presence of a responsive and well-established pediatric mental health team within the clinic where we are recruiting will support the needs of subjects who are identified with possible emotional or behavioral symptoms or disorders that are identified but that do not qualify for our intervention study. At any time during our brief screen, the parent or the child may discontinue the interview/assessment or choose not to talk about a certain topic. To protect against any psychological risk, interviewers are carefully trained. All have a four-year degree. They receive intensive training, which includes training in research ethics and confidentiality. All of our interviewers will also have experience with and excellent rapport with young children.

The interviewers are also trained in procedures for cases where a participant indicates suicidal or homicidal thoughts or plans. Cases of suspected suicidal or homicidal ideation are reported to Nancy Zucker, PhD, who is a licensed child psychologists on the study faculty. If necessary, a referral will be made to a local mental health provider. One of the reasons we chose the Duke Pediatric Clinic as our recruitment site is that it has an in-house mental health team led by Dr. Walter, who is also a member of our research team. Thus, the parents and children in the study can be referred to Dr. Walter's team for mental health evaluation and treatment. This mental health team, as well as the Duke Child Guidance Clinic, provides services for children with and without health insurance. If a child or parent is referred for mental health evaluation, a report is filed with the subject's informed consent forms. Barbara Keith Walter PhD, who leads the clinic's mental health team, will serve as a critical liaison between our research group and the clinic. She played this role in the PAPA test-retest study and is currently supervising the study of older children (Zucker; RC1-MH-088678). She will help to ensure that we collaborate efficiently and effectively with the pediatricians, child psychiatrists and psychologists, nurses, and other clinic staff. She will also facilitate mental health evaluations or treatments if they appear necessary at any point in the study. In the set-up time at the beginning of the study, we will meet with the clinic staff to introduce ourselves and the study protocol and to answer any questions and address any concerns. An information sheet including the name of the study, the purpose of the study, and the names, numbers, and e-mail addresses of the principal and co-investigators and the study coordinator will be printed on colored cardboard and posted throughout the clinic. Critically, Dr. Zucker has collaborative relationships with all these pediatricians due to her clinical work with childhood eating and somatic disturbance so lines of communication are both familiar and frequently utilized.

B.2b) Protection Against Psychological Risks: Diagnostic Assessments and Treatment

Diagnostic Assessments. At any time, the parent or the child may discontinue the interview/assessment or choose not to talk about a certain topic (see above for training of interviewers). The interviewers are also trained in procedures for cases where a participant indicates suicidal or homicidal thoughts or plans. Cases of suspected suicidal or homicidal ideation are reported to Nancy Zucker, PhD, who is a licensed child psychologist on the study faculty. If necessary, a referral will be made to a local mental health provider. In practice, our research group, which has more than two decades of experience with interviewing parents and children, has found that raising "sensitive" subjects (e.g., depression, suicidal ideation) with children or parents for whom this is a problem area serves as a relief to them, providing validation that the problem is "real", and a source of help for it to be made available (see below).

Treatment. For protection of the mental health of dyads during treatment, the clinical research team will have weekly case consultation meetings. Attending these meetings with be the PI (a child psychologist and any relevant study therapists, and, if needed, a pediatrician who works closely with our research group (Maslow). Psychological symptoms and pain ratings will be reviewed to monitor the success of current therapeutic strategies and to discern the need for referral for additional or alternative sources of care. In those cases for which a referral is required, we will carefully document such treatments and will include their intervention data up to the point in which this referral was made.

B.3. Protection Against Social Risks

Interviewers are trained not to talk to anyone about their interviews and sign confidentiality agreement to that effect. All data that would lead to subject identification will be labeled using a research code number only so that no names will be used in any of the data. Confidentiality of all subject information will be preserved by housing all records and interview tapes in locked files in locked offices. Data will be

maintained on a computer accessible only to research project staff. Further, all computerized data will be maintained in a limited access, password-protected hard drive or on secure backup drives locked in files in the research office of study PIs.

B.4. Protection Against Legal Risks

Procedures to preserve confidentiality. Interview schedules and tapes will be closely protected at all times. After collection, coding, and review for accuracy by the project coordinator, data are entered double-entered into computer files at our offices at Duke, except for the ePAPA which are computerized and do not require double data entry. The schedules and tapes are then stored in locked storage facilities. Participant information on the computer files is identified only by a study-specific identification number. Only approved research staff has access to the data. All faculty and staff have taken and passed Duke's required training modules on HIPAA regulations for protecting participants' privacy, and the Center for Developmental Epidemiology, where the study records are held, observes all approved security rules to protect the data. The Center for Developmental Epidemiology has a full-time staff member, our medical information systems manager Jurgen Henn, who oversees our group's HIPAA compliance.

Costs to the Subject

- Describe and justify any costs that the subject will incur as a result of participation; ordinarily, subjects should not be expected to pay for research without receiving direct benefit.

There are no costs to the subjects.

Data Analysis & Statistical Considerations

- Describe endpoints and power calculations. Provide a detailed description of how study data will be analyzed, including statistical methods used, and how ineligible subjects will be handled and which subjects will be included for analysis. Include planned sample size justification. Provide estimated time to target accrual and accrual rate. Describe interim analysis including plans to stop accrual during monitoring. Phase I studies, include dose escalation schema and criteria for dose escalation with definition of MTD and DLT.

Statistical Methods

Tests of hypotheses will be based on standard binomial models for proportions and Student's t-test or standard ANCOVA regression models as appropriate for continuous measures; ordinal data not meeting assumptions of normality will be analyzed using nonparametric Wilcoxon Mann-Whitney procedures or, in some cases, generalized linear regression (Poisson, logistic) models. For the R33, evaluations will be repeated 6-months post-treatment.

Data & Safety Monitoring

- Summarize safety concerns, and describe the methods to monitor research subjects and their data to ensure their safety, including who will monitor the data, and the frequency of such monitoring. If a data monitoring committee will be used, describe its operation, including stopping rules and frequency of review, and if it is independent of the sponsor (per 45 CFR 46.111(a) (6)).

Data and Safety Monitoring Board. We have established a DSMB that we have used in our prior clinical trials that includes a registered nurse and former member of the Clinical Research Support Office (Sharon Minda, RN), a principal investigator of epidemiological trials of child mental health (William Copeland, PhD), Kerri Boutelle, PhD, a pediatric clinical trials researcher from the University of California, San Diego and Alex Kemper, MD, a former leader in the Duke Pediatric Clinical Trials Network. This committee will meet twice annually or as needed to review the conduct of the trial and any unanticipated events. Such review will include random review of sessions, investigation of child and parent post-session ratings of satisfaction, as well as the screening procedures in primary care. By having clinical staff involved in every

aspect of this trial from recruitment to treatment, we hope to avoid and address any foreseeable problem that should arise. All study staff is instructed to inform the PIs of any event as soon as possible. Weekly staff meetings including review of interview and session tapes also ensures safety.

Privacy, Data Storage & Confidentiality

- Complete the Privacy and Confidentiality section of the iRIS submission form.

Describe Role of External Personnel:

Outside Duke Key Personnel:
Stephen W. Porges, Greg Lewis, and Maria Isabel Davila Hernandez are helping to analyze the Presentation and Acquisition lab data from our Mood Induction Labs. This data does not contain any PHI and is labeled by the subject's study ID numbers.
Helen Egger, M.D is a consultant for our study who has no access to subject's PHI.
Nancy Spencer is a consultant who will be working with us as a therapist for our Caregiver n Action (CIA) Therapy Sessions. She will have access the following PHI during her work on The Duke Tummy Pain Study: Subject names, telephone number, & audio recordings of her therapy sessions with subjects.
July 8, 2019
Kyra Citron:Duke Undergraduate Student volunteer. She will be doing data entry in REDCap. She will NOT have access to any PHI.
Bruny Kenou: Duke Undergraduate Student volunteer. She will be doing data entry in REDCap. She will NOT have access to any PHI.
Ashley Kelley:Duke Undergraduate Student volunteer. She will be doing data entry in REDCap. She will NOT have access to any PHI.
Tejaswi Siripurapu:Student volunteer. She will be doing data entry. She will NOT have access to any PHI.

Study Scope

Does the subject population contain >50% malignant hematology or oncology patients, or their caregivers?

○ Yes ◉ No

Are you using a drug, biologic, food, or dietary supplement in this study?

○ Yes ◉ No

Are you using a medical device, an algorithm (whether computer based or not), an in vitro diagnostic test, or using samples to look for biomarkers in this study?

○ Yes ◉ No

Does this study employ magnetic resonance, including imaging (MRI), spectroscopy (MRS), angiography (MRA) or elastography (MRE) beyond the standard of care?

○ Yes ◉ No

Does this study specify or require the performance of diagnostic procedures using ionizing radiation (x-rays, DEXA, CT scans, nuclear medicine scans, etc.) that are beyond the standard of care?

○ Yes ◉ No

Does this study specify or require the performance of therapeutic procedures using ionizing radiation (accelerator, brachytherapy or systemic radionuclide therapy) that are beyond the standard of care?

○ Yes ◉ No

Will the participant be subjected to increased or decreased ambient pressure?

○ Yes ◉ No

Do you plan to recruit subjects from Duke Regional Hospital (DRH)?

○ Yes ◉ No

Do you plan to recruit subjects from Duke Raleigh Hospital (DRAH)?

○ Yes ◉ No

Does this study utilize the Duke Early Phase Clinical Research Unit (DEPCRU)?

○ Yes ◉ No

Are you using the Duke logo in any advertisements?

○ Yes ◉ No

Is this study retrospective, prospective, or both?

"Retrospective" means that data or samples already in existence (collected prior to the study submission) will be used.
"Prospective" means there will be data or samples collected in this study for research purposes.

○ Retrospective
○ Prospective
◉ Retrospective and Prospective

If the study is both retrospective and prospective: Is this a review soley of information collected for non-research purposes (i.e. a review of medical records)?

○ Yes ◉ No

Does this protocol include any research using botulinum toxin, including the FDA-approved clinical product (Botox)?

○ Yes ◉ No

Does this protocol involve the administration of any of the following materials to humans?

•Any viral vector or plasmid
•Any cells that have been modified by a viral vector
•Any other genetically-modified cells
•Any genetically-modified virus, bacterium, or other agent
•Any other recombinant or synthetic nucleic acid

○ Yes ◉ No

Subject Population Groups and Enrollment

Population Groups (Select targeted population groups only):

Note:

- If Minors are included, the study will be routed to the Department of Pediatrics for Pediatric Risk Assessment.
- Students and Employees over whom Key Personnel have a supervisory role may not be enrolled in this study

- [x] Adults
- [ ] Minors who are Wards of State
- [x] Minors
- [x] Duke Patients
- [ ] Pregnant Women
- [ ] Fetuses
- [ ] Prisoners
- [ ] Adults incapable of giving consent
- [ ] Adults with diminished capacity
- [ ] Handicapped subjects
- [ ] Students
- [ ] Employees
- [ ] Healthy Controls
- [ ] Deceased subjects
- [ ] Blanket Protocol

This study will be routed to the Department of Pediatrics for Pediatric Risk Assessment.

Please select any population groups excluded from participation in this study:

- [ ] Pregnant women

Maximum number of subjects to be consented at Duke:

Enter a single number. If you anticipate consenting a range of subjects, enter the **upper** limit of the range. The number should represent the maximum number of subjects for the life of the study.

2000

Maximum number of subjects to be consented at all sites:

Enter a single number. If you anticipate consenting a range of subjects, enter the **upper** limit of the range. The number should represent the maximum number of subjects for the life of the study.

2000

Maximum number of patient records / samples to be used:

2000

Subject Procedures and Costs

Biobank - Does this study involve the collection, use, tracking, banking (storage) or distribution of human biological specimens?

Human biological specimens include blood or its components, healthy or diseased tissue, bodily fluids, DNA /RNA or human stem cells.

○ Yes ◉ No

Procedures

Check all the apply:

- ☐ Genetic Testing
- ☐ Gene Transfer
- ☐ DNA Banking
- ☐ Testing for Reportable Infectious Diseases
- ☐ Human Cell Banking
- ☐ *Use of Human Embryonic Stem Cells
- ☐ *Use of Human-induced Pluripotent Stem Cells
- ☐ *Use of Other Cells Derived from Human Embryos
- ☐ *Use of Human/Animal Chimeric Cells
- ☐ *Specialized Cell Populations for Cell Therapy
- ☐ Use of Human Tissue
- ☐ Use of Bodily Fluids
- ☐ Use of Blood (or its components)
- ☑ Not Applicable

Will blood be drawn in this study for research purposes?

○ Yes ◉ No

Will the Operating Room be used in this study?

Include only research time, not clinical care time.

○ Yes ◉ No

Will there be extra costs to subjects or insurance as a result of the research (e.g. tests, hospitalization)?

○ Yes ◉ No

Will there be Subject Compensation?

◉ Yes ○ No

Compensation for Travel / Lost Income (in USD):

380

Other Subject Compensation:

No monetary compensation will be provided for the 10 intervention sessions, but children will be given an assortment of toys at the end of each in-person session.

Both parent and child that participate in this study will be receiving compensation. Upon completion of the study parents will receive a $55 pre-loaded ClinCard. Upon the child's completion of a focus group /interview session they will receive a small toy.

Amendment June 2019: Individuals that participate in the online survey to inform the development of an intervention for individuals of Hispanic origin will receive a $25 gift card from Amazon.

Subject Recruitment Materials

For each document to be reviewed, use the table below to provide the following information:

Attach a copy of each advertisement that you will be using with this study in the Initial Submission Packet. If any Ad will have multiple wording variations, attach a copy of each version of the Ad.
All materials that will be used to advertise the study in order to recruit subjects must be approved by the IRB.

Types of subject recruitment materials include, but are not limited to, the following:

Direct Advertising
Posters
Billboards
Flyers
Brochures

Media Advertising
Newspaper Ads
Magazine Ads
Radio Ads
TV commericals / Video
Internet website
Social Media

Other Types of Advertising
Newsletter
Email
Postcards / Letters

(Note: Doctor-to-Doctor letters do not require IRB approval)

Document name	Material category	Location material displayed	Has this material previously been approved by the IRB?
(SV-FT) DTP Chat Groups Brochure 6.1.18	○ Billboard / Flyer / Poster ◉ Brochure ○ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. Brochure given to subject upon screen in to study.	○ Yes ◉ No
	◉ Billboard / Flyer / Poster ○ Brochure ○ Internet website / Email	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital	

(SV-FT) DTP Chat Groups Flyer 5.31.18	○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Television" would be an appropriate response. Flyer will be posted on back of door in patient room at Duke's Southpoint Clinic and Durham Pediatrics.	○ Yes ◉ No
(EV) DTP Chat Groups Flyer 5.31.18	◉ Billboard / Flyer / Poster ○ Brochure ○ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. Flyer will be posted on back of door in patient room at Duke's Southpoint Clinic and Durham Pediatrics.	○ Yes ◉ No
(EV) DTP Chat Groups Brochure 6.1.18	○ Billboard / Flyer / Poster ◉ Brochure ○ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. Brochure given to subject upon screen in to study.	○ Yes ◉ No
English Version-Flyer for Online Study	○ Billboard / Flyer / Poster ○ Brochure ◉ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. Flyer that will be posted in DukeList, other community listservs, will be emailed to interested participants, and will	○ Yes ◉ No

		be posted in the Lakeview Pavillion Waiting Room	
Spanish Version- Flyer for Online Study	○ Billboard / Flyer / Poster ○ Brochure ◉ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. Flyer that will be posted in DukeList, other community listservs, will be emailed to interested participants, and will be posted in the Lakeview Pavillion Waiting Room	○ Yes ◉ No

Consent Process

Attach draft consent forms in the Initial Review Submission Packet.

Consent forms must be MS Word documents and follow the specific format outlined by the IRB. **Click here** to download a copy of the consent form template.

Note: Please do not edit the section of the footer that contains the Protocol ID, Continuing Review and Reference Date fields. Those fields will be used to stamp the final consent form when it is approved by the IRB. If you want to add an internal version date, please put it in the header.

Who will conduct the consent process with prospective participants?

Give the person's role in this study (PI, Study Coordinator, etc.):

The study coordinator or senior research assistant.

June 2019: Parents completing the Qualtrics survey for the diversity supplement will read and electronically sign the consent form as part of the survey.

Who will provide consent or permission?

(Select all that apply):

- ☑ Participant
- ☑ Parent(s) or Legal Guardian(s)
- ☐ Legally Authorized Representative (LAR)

How much time will the prospective participant (or legally authorized representative) have between being approached about participating in the study and needing to decide whether or not to participate?

If you are not giving the person overnight to consider whether or not to participate, please justify.

The parent and child will have anywhere from a few days to a few weeks to decide whether to participate.

June 2019: Participants will have as long as needed to contemplate the consent form as they can access the study link with embedded consent form at any time.

Where will the consent process occur?

Consent for screening will occur in the exam room of a pediatric care practice within the Duke Health System. Consent for the treatment will occur in a private testing room in the Duke Center for Eating Disorder Research Laboratory in Brightleaf Square.

June 2019: Parents completing the Qualtrics survey for the diversity supplement will be able to read and complete the consent form wherever they prefer, but must complete the electronic consent form in order to proceed to the online survey.

What steps will be taken in that location to protect the privacy of the prospective participant?

We will conduct consent in a private room with a closed door. This room is in a testing suite in which the only individuals present are those participating in the study and thus a low traffic area.

June 2019: For the online portion of the diversity supplement, individuals will choose the setting in which they read and sign the consent.

How much time will be allocated for conducting the initial consent discussion, including presenting the information in the consent document and answering questions, with each prospective participant?

A minimum of a day (in between screening and scheduling for the intake visit) but typically a week or more. The subject may take as long as needed to consider the consent form and study demands.

What arrangements will be in place for answering participant questions before and after the consent is signed?

During the process of consent, we stop frequently and ask if the participant has any questions and restate the language of the consent form using words that are easy to comprehend. The participant is given the PI's cell number to call if questions.

June 2019: Study staff contact information will be provided on the electronic consent form for individuals completing the diversity supplement Qualtrics survey.

Describe the steps taken to minimize the possibility of coercion or undue influence.

We emphasize the participants right to refuse to participate and that this will not impact their care at Duke.

What provisions will be in place to obtain consent from participants who do not read, are blind or who do not read/understand English?

Unfortunately, these individuals would not be eligible for our study as the interventions require the capacity to read English.
As of April 2018 we have been approved and funded by the NIMH to include a diversity supplement under the FBI parent study. Through this supplement, we will be conducting a series of focus groups and interviews with Hispanic participants. The focus groups will be translated into Spanish. Consent forms have been tranlated into Spanish.

June 2019: The online consent form and questions have been translated and back-translated into Spanish.

Do you plan to obtain written consent for the conduct of research?

(•) Yes ( ) No

Protected Health Information (PHI)

Indicate how you intend to use potential subjects' Protected Health Information (PHI):

(•) I will review, but not record, PHI prior to consent.
( ) I will record PHI prior to consent.
( ) I do not intend to use PHI prior to consent.
( ) I will record PHI without consent. (decedent research, database repository, chart review)

Review Preparatory to Research (RPR)

Describe the specific PHI that will be reviewed to prepare a research protocol and/or to ascertain and/or recruit subjects:

Child's name and age

Principal Investigator's Affirmation:

The PHI is necessary for the purposes of this activity.

(•) Yes ( ) No

The PHI will be used solely for this activity.

(•) Yes ( ) No

The PHI will not leave DUHS.

(•) Yes ( ) No

The PHI will not be written down or recorded prior to the subject signing a research consent form.

(•) Yes ( ) No

I will not use the information accessed through this RPR procedure for any other purpose, including for presentation or publication.

(•) Yes ( ) No

Privacy and Confidentiality

Explain how you will ensure that the subject's privacy will be protected:

Consider privacy interests regarding time and place where subjects provide information, the nature of the information they provide, and the type of experience they will be asked to participate in during the research.

We adhere to all Duke procedures for the management of study-related data, keeping this data in locked areas accessible only to study personnel.

Describe how research data will be stored and secured to ensure confidentiality:

How will the research records and data be protected against inappropriate use or disclosure, or malicious or accidental loss or destruction? Records and data include, for example, informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheets, screening logs or telephone

eligibility sheets, web based information gathering tools, audio/video/photo recordings of subjects, labeled specimens, data about subjects, and subject identifiers such as social security number.

All paper documents are kept in locked file cabinets in storage rooms dedicated to the storage of study related materials. Databases are kept on a secure folder on a secure drive established by Jurgen Henn, the IT consultant for the Department of Psychiatry. Social security numbers are redacted as soon as a subject's payment has been processed.

Application Questions Complete

Please click Save & Continue to proceed to the Initial Submission Packet.

The Initial Submission Packet is a short form filled out after the protocol application has been completed. This is an area to attach protocol-related documents, consent forms, and review the application.