04/15/2019

Enclosed is the Institutional Review Board application for our study evaluating the treatment of severe destructive behavior: FCT versus wait-list control (363-15-FB; NCT02483572). This document was last approved by our Institutional Review Board on February 28, 2018 and downloaded on April 15, 2019. Note that the watermark indicates the application is "Inactive" because we closed the study's application through our Institutional Review Board.

University of Nebraska Medical Center

Munroe-Meyer Institute
985450 Nebraska Medical Center, Omaha, NE 68198-5450

Pediatric Behavioral and Social Science Research
SECTION I

1. Status:

♦ New Submission
Revised electronic IRB Application; IRB#
Initial electronic submission of an existing expedited IRB approved protocol; IRB#

2. Title of Protocol:

Treatment of severe destructive behavior: A randomized clinical trial of functional communication training versus wait-list control

3. Responsible Personnel:

A. Principal Investigator (PI):

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G. Are you a student?
No

4. Funding Source:
Check all that apply and provide the source of the funding.
Grant - Provide Source:
Commercial - Provide company name:
Department of Defense
♦ Other - Provide Source: Departmental funds
Center for Clinical and Translations Research (CCTR)

5. Contract:
Is there a contract or agreement associated with this study?

No

6. Funding Agency Deadline for IRB Approval:
Yes
♦ No

7. Study Sites:
A. Provide the names and locations of all study sites where this research will be conducted under the oversight of the Joint Pediatric IRB.
University of Nebraska Medical Center's Munroe-Meyer Institute

B. Is this a multi-site study?
No

C. Does this study involve any international sites where the PI will either conduct or supervise the study?
No

8. Principal Investigator Assurance
The PI understands and accepts the following obligations to protect the rights and welfare of research subjects in this study:

- **I certify that I have carefully reviewed this application and all supporting documents. I have determined that the application is accurate, complete and ready for submission to the IRB.**
- **I certify that I, and all listed research personnel, have the necessary qualifications and expertise to conduct this study in a manner which fully protects the rights and welfare of research subjects.**
- **I certify that all listed research personnel will be given a copy of the final IRB approved application and any other relevant study related documents in accordance with their defined responsibilities.**
- **I recognize that as the PI it is my responsibility to ensure that this research and the actions of all research personnel involved in conducting the study will comply fully with the IRB-approved protocol, all applicable federal regulations, state laws, and HRPP policies.**

- **I recognize that it is my responsibility to ensure that valid informed consent/assent has been obtained, as appropriate, from all research subjects or their legally authorized representative (LARs). I will ensure that all research personnel involved in the process of consent/assent are properly trained and are fully aware of their responsibilities relative to the obtainment of informed consent/assent according to applicable federal regulations, state laws, and HRPP policies.**

- **I certify that the minimum amount of protected health information (PHI) or other identifiers necessary will be used and disclosed to conduct this research study (if applicable). I will implement reasonable safeguards to protect the PHI/other identifiers at all times.**

- **I will promptly inform the IRB of any unanticipated problems involving risk to the subjects or to others, as required within the time frame defined by HRPP policies. I will analyze each reported problem to determine if it impacts the risk-benefit relationship of the study, the safety of the subjects, or informed consent.**

- **I will promptly inform the IRB if I become aware of 1) any complaints from research subjects, LARs, or others about research participation, 2) violations of federal regulations or state law, 3) violations of the HIPAA Rule, or 4) violations of HRPP policies.**

- **I will not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject, in which case the IRB will be notified as soon as possible.**

- **I certify that there are, or will be, adequate resources and facilities to safely initiate, carry out and complete this research at the study sites specified in Section I.7. This includes sufficient staff, funding, space, record keeping capability, and resources necessary to address any unanticipated problems involving risk to the subject or others. If the necessary resources become unavailable I will promptly notify the IRB.**

- **I will promptly inform the IRB of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.**

- **I understand that continuing review by the IRB is required at least annually in**

order to maintain approval status. I will maintain IRB approval as long as this study is active.

- **I certify that I and all other personnel listed in Section I.3A-E of the IRB Application have disclosed all potential financial conflicts of interest as required and are in full compliance with the UNMC Conflict of Interest Policy and HRPP policy. I further certify that all potential financial conflicts of interest are appropriately managed in order to ensure protection of the rights and welfare of subjects.**

- **I will maintain all required research records on file and I recognize that representatives from the IRB, OHRP, HHS, and other Federal Departments or Agencies may inspect these records in accordance with granted authority.**

- **I understand that failure to comply with the Common Rule, applicable Subparts B, C, and D of HHS regulations at 45 CFR 46, the HIPAA Rule, applicable state law, HRPP policies, and the provisions of the IRB-approved protocol may result in suspension or termination of IRB Approval of my research project and/or other administrative or legal actions.**

Fisher, Wayne W - 2018-08-30 09:40:00.000

10. Principal Investigator Financial Interest Disclosure
A. As the PI, I certify that I am in full compliance with UNMC Conflict of Interest Policy #8010 and I declare:
♦ I have no financial interest in this research.
I have a financial interest in this research. I have completed the UNMC Disclosure of Potential Conflict of Interest Form and obtained all required signatures. The original disclosure form is attached to this application.

B. As the PI,
♦ I understand that if there is any change in my financial interest during the course of this research, I will update and submit the UNMC Disclosure of Potential Conflict of Interest Form within five (5) business days from the time the change becomes known.

C. As the PI who is ultimately responsible for the proper conduct of this research, I also certify that:
♦ No Responsible Personnel have a financial interest in this research.
The Responsible Personnel listed below have informed me that they have a financial

interest in this research.

D. I have informed all Responsible Personnel that if there is any change in their financial interests during the course of this study it must be disclosed by submitting or updating the required UNMC Disclosure of Potential Conflict of Interest Form.
Fisher, Wayne W - 2018-08-30 09:40:00.000

11. Scientific/Scholarly Merit and Resource Review Certification
A. Scientific Reviewer:
Leibowitz, J (J Michael) Michael - Munroe-Meyer Institute - 402-559-5702 - mleibowi@unmc.edu - alt #: 402-559-5702 - degree: PhD - address: - phone:

B. My signature certifies that this application has been reviewed for scientific/scholarly merit and available resources. It has been determined that the application merits consideration by the IRB based upon the following:

- **1) The proposal has an acceptable level of scientific/scholarly merit which justifies the use of human subjects.**
- **2) The proposal has a sound research design in consideration of the stated objectives,**
- **3) The PI has the necessary qualifications and experience to conduct this research.**
- **4) The PI has, or will have, the necessary funding to support this research.**
- **5) There is or will be adequate physical space required for the research interventions at all study sites specified in Section I.7. In addition, there is adequate laboratory and clerical support, data storage capability, and any other resources necessary to complete this research.**
- **6) At all study sites specified in Section I.7, there are provisions to respond promptly to unanticipated problems involving risk to the subject or others.**
- **7) I will promptly notify the IRB if the necessary resources to support this research become unavailable.**

I am not listed as study personnel in Section I of this application.

Leibowitz, J (J Michael) Michael - 2015-05-11 13:32:00.000

SECTION II

PROTOCOL ABSTRACT

1. Provide a brief (less than 400 words) abstract of the research protocol. This summary should include: 1) the title of the protocol, 2) a *brief* description of the purpose of the study, 3) eligibility criteria, 4) interventions and evaluations and 5) follow-up.

Treatment of Severe Destructive Behavior: Functional Communication Training Versus Waitlist Control

Children with an intellectual disability often display severe destructive behavior (e.g., aggression, self-injury) that pose risks to themselves or others and represent barriers to community integration. Destructive behaviors are often treated with behavioral interventions derived from a functional analysis, which is used to identify the antecedents and consequences that occasion and reinforce the destructive behavior. One such treatment is called functional communication training (FCT), which involves extinction of destructive behavior and reinforcement of an alternative communication response with the consequence that previously reinforced destructive behavior. Results from epidemiological studies and meta-analyses indicate that treatments based on functional analysis, like FCT, typically reduce destructive behavior by 90% or more and are more effective than other treatments. However, many if not all of these studies have used within-subject experimental designs to demonstrate control of the treatment effects. Replication of the effects of FCT is typically shown on a subject-by-subject basis with relatively small numbers of patients (e.g., one to four patients). To our knowledge, no study has demonstrated the effectiveness of FCT for treatment of destructive behavior across a large group of children.

The goal of this study is to compare FCT (which is used clinically with the majority of our patients and is considered best practice for treating destructive behavior that occurs for social reasons [e.g., to access attention, preferred toys, or to escape from unpleasant activities]) to a waitlist control group across a large number of children with destructive behavior to evaluate the generality of FCT effectiveness. We will evaluate rates of destructive behavior with each patient during a pretest baseline and again following FCT (approximately four months later) and/or the waitlist control duration (again, approximately four months later). All children assigned to the waitlist-control condition will be offered FCT services by our clinic at the end of the four-month waitlist period. These children will again be tested following four months of FCT (i.e., posttest). Therefore, children assigned to the FCT condition will be tested twice (one pretest and one posttest), and children assigned to the waitlist-control condition will be tested thrice (one pretest, a second pretest following a four-month waitlist period, and one posttest).

We will pair participants to dyads and randomly assign one participant to the FCT condition and one participant to the waitlist control condition. The exact duration of the waitlist condition for one participant will be matched to the duration of the FCT participants admission. Historically, most children complete FCT within four months.

PURPOSE OF THE STUDY AND BACKGROUND

2. Purpose of the Study

What are the specific scientific objectives of the research?

The purpose of the current investigation is to evaluate the generality of FCT as treatment for severe destructive behavior. Again, the effectiveness of FCT in treating destructive behavior has been demonstrated repeatedly both in our clinic and in other clinics. We are specifically interested in examining the percentage of this population that might benefit from FCT, as well as identifying the subject characteristics of children for whom FCT is and is not effective.

3. Background and Rationale

Describe the background of the study. Include a critical evaluation of existing knowledge and specifically identify the information gaps that the project is intended to fill.

Children with an intellectual disability often display severe destructive behaviors (e.g., aggression, self-injury) that pose significant risks to self or others and represent overwhelming barriers to community integration. These destructive behaviors are often treated with behavioral interventions derived from a functional analysis, which is used to identify the environmental antecedents and consequences that occasion and reinforce the destructive behavior (Iwata, Dorsey, Slifer, Bauman, & Richman, 1982/1994). One such treatment is called functional communication training (FCT), which involves extinction of destructive behavior and reinforcement of an alternative communication response with the consequence that previously reinforced destructive behavior (Carr & Durand, 1985). Results from epidemiological studies and meta-analyses indicate that treatments based on functional analysis, like FCT, typically reduce destructive behavior by 90% or more and are much more effective than other treatments (Tiger, Hanley, & Bruzek, 2008). Despite these impressive findings, there have been no randomized, controlled trials evaluating the effectiveness of FCT. The goal of this study is to determine the robustness of FCT in reducing severe destructive behavior as compared to a waitlist control group.

CHARACTERISTICS OF THE SUBJECT POPULATION

4. Accrual

A. Is this study conducted <u>solely</u> at sites under the oversight of the Joint Pediatric IRB

(e.g. UNMC, TNMC, CH&MC, UNO)?
Yes

1) What is the <u>total</u> number of subjects (per group, as applicable) needed to complete the research in order to achieve the scientific objectives of the research?
We will initially randomize four participants to the immediate-treatment condition and four participants to the wait-list control condition (total of 8 initial participants). Following these eight participants, we will then conduct a power analysis to determine how many additional participants are needed to achieve statistical power. Though our statistical analysis will guide how many total participants we will need, we expect no more than 30 total children (15 in each condition) will be needed to complete this study.

2) What is the statistical or other justification for the <u>total</u> number of subjects needed to complete the research in order to achieve the scientific objectives of the research?
The total number of participants will be guided by our statistical power analysis. This power analysis will be conducted following eight participants to determine if we need additional data. We acknowledge that this may require a change in protocol in section II.4 (accrual).

3) Based on the anticipated number of subject withdrawals or other factors, what is the maximum number of subjects that will need to be consented in order to achieve the scientific objectives of the research?
We expect a maximum of 30 participants will be consented.

5. Gender of the Subjects
A. Are there any enrollment restrictions based on gender?
No

6. Age Range of Subjects
A. What is the justification for inclusion of children in this research?
All participants will be between 3 and 18 years of age when they are enrolled in the project. We chose this age range because most individuals with severe destructive behavior are initially referred at or around this age. The Severe Behavior Disorders Program primarily serves children and youths and is specifically designed for this group.

B. What is the age range for the child subjects, and what is the justification for selecting this age range?
The age range is 3-18 years old. We chose this age range because most individuals with severe destructive behavior are initially referred at or around this age.

C. Will this study enroll wards of the state?
No

D. Will adults (19 years of age or older) be included in this research?
Yes

1) What is the justification for including adults in the research?
The child's parents/caregivers will be included in the research to conduct pretest and posttest sessions. The purpose of the inclusion of adults is to confirm that FCT effects generalize from the therapists to the caregivers.

2) What is the age range of the adult subjects to be included in the research?
19 to 70 years old

3) What is the rationale for the age range of the subjects?
This range encompasses the ages of legal guardians of children (parents or grandparents) seen in our clinic.

7. Race and Ethnicity
Are there any subject enrollment restrictions based upon race or ethnic origin?
No

8. Vulnerable Subjects
A. Will any of the following vulnerable populations be allowed to participate in this research? Check all that apply.
Pregnant individuals; fetuses
Prisoners
♦ None

B. Will any of the following vulnerable populations (Students of the investigator, Educationally disadvantaged individuals, Socially or economically disadvantaged individuals, Individuals with a stigmatizing illness or condition, Other) be <u>specifically</u> recruited for enrollment in this research?
No

9. Inclusion Criteria
What are the specific inclusion criteria?
<u>Child Subjects:</u>

1. Boys and girls between the ages of 3 and 18;

2. Destructive behavior (e.g., aggression, property destruction, SIB) that has been the focus of outpatient behavioral and pharmacological treatment but continues to occur, on average, more than once per hour;
3. Destructive behavior reinforced by social consequences (i.e., significantly higher and stable rates of the behavior in one or more social test conditions of a functional analysis [e.g., attention, escape] relative to the control condition [play] and the test condition for automatic reinforcement [alone or ignore]);
4. On a stable psychoactive drug regimen (or drug free) for at least 10 half-lives of each medicationwith no anticipated changes;
5. Stable educational plan and placement, with no anticipated changes during the study.
6. Currently enrolled or on the waiting list for the Severe Behavior Clinic.

Adult Subjects (Caregivers):

1. Men and women between the ages of 19 and 70;
2. Who do not have any physical limitations that would prohibit them from conducting sessions with their child (i.e., pregnant);
3. Have a child who is currently enrolled or on the waiting list for the Severe Behavior Clinic.

10. Exclusion Criteria

What are the specific exclusion criteria?

Child Subjects:

1. Children not meeting the inclusion criteria above;
2. Children currently receiving intensive (15 or more hours per week), function-based, behavioral treatment for their destructive behavior through the school or another program;
3. DSM-V diagnosis of Rett syndrome or other degenerative conditions (e.g., inborn error of metabolism);
4. Presence of a comorbid health condition (e.g., blindness) or major mental disorder (e.g., bipolar disorder) that would interfere with participation in the study (e.g., requiring frequent hospitalizations);
5. Children with SIB who, based on the results of the risk assessment, cannot be exposed to baseline conditions without placing them at risk of serious or permanent harm (e.g., detached retinas);
6. Children requiring changes in drug treatment (but such children will be invited to participate if they meet the above criteria 3 months after a stable drug regimen is achieved).

Adult Subjects (Caregivers):

1. Adults who are outside the age range of 19 to 70
2. Pregnant mothers (for safety purposes)

METHODS AND PROCEDURES

11. Methods and Procedures Applied to Human Subjects
A. Describe sequentially all procedures, interventions, evaluations and tests.
Parent Baseline Pretest
Prior to FCT treatment or waitlist-control assignment, children and their parents will attend clinic for 1 hour to conduct approximately 8 sessions that are each 5 minutes. During these sessions, parents will interact with their children within four conditions. Therapists will use a Bluetooth device to instruct the parents to implement the functional-analysis test conditions (described in the sections below) as intended. During the attention condition, the parent will be instructed to fill out relevant clinic documents rather than playing with the child and the child's toy. Following target problem behavior, the therapist will prompt the parent to provide 20-s of attention. During the escape condition, the parent will be instructed to deliver a variety of tasks or chores to the child that the parent reported as problematic according to a 3-step guided compliance procedure. Following target problem behavior, the therapist will prompt the parent to provide a 20-s break. During the tangible condition, the parent will remove a preferred toy from the child's reach and interact with the toy. Following problem behavior, the therapist will prompt the parent to provide 20-s access to the toy. During the toyplay (control) condition, parents will play with their children and provide continuous access to the preferred toy from the tangible condition, a continuous break from instructions, and attention every 30 s. Therapists will prompt parents to continue playing with the child if the child engages in target problem behavior. Therapists will conduct approximately 15 to 30 sessions during each clinic visit for each child. Participants will be seen for 1.5 to 3 hour visits, 1 to 5 days per week (depending on the client and parent's schedules) for 8 to 12 weeks. Parents typically spend 3 hours in the clinic during the first week of treatment in order to determine goals for the child, to review treatment procedures, and to interact with the child under controlled observations to inform assessment and treatment protocols.

We may also ask parents to complete a battery of tests to provide additional information on the child's level of problem behavior prior to treatment. Specifically, we hope to obtain additional information on the nature of the participant's problem behavior, how the problem behavior affects the life of the participant and family, and any psychological stress or difficulties as a result of the participant's problem behavior. The specific assessments used will be the: (1) Home Situations Questionnaire, (2) Parental Stress Inventory, (3) Nisonger Child Behavior Rating Form, (4) Vineland Adaptive Behavior Scales II, and (5) Functional Analysis Screening Tool. Please see the attached documents for a copy of these assessments. Each assessment will take caregivers a maximum of 30 minutes to complete, for a maximum total duration of 2.5 hours. Each questionnaire, except for the Functional Analysis Screening Tool (FAST) will be completed twice, once prior to admission and once following successful treatment. We will offer the option for caregivers to complete these

questionnaires over the course of two days each time we administer the questionnaires (at the beginning and end of admission). The FAST will not be administered twice, as the functional variables maintaining the child's problem behavior typically do not change in the brief time the child is seen for treatment. With parental permission, we will also work with the participant's school to acquire previously implemented inventories on communication skills, grade level equivalence, intelligence quotient, and general school performance information. Acquiring additional information of this sort is becoming best clinical practice in the Center for Autism Spectrum Disorders. If the parent responds in a way that indicates high stress on the Parental Stress Inventory and these scores remain high following successful treatment and parent training, we may consult with the caregiver to determine what specific variables are contributing to the maintenance of high stress and offer resources or referrals accordingly. For example, if the parent's stress seems to stem from lack of time for other siblings, work, or personal matters and this continues following successful treatment, we may consult with the parent and make a referral to Munroe-Meyer Institute's Mark Smith to learn about respite services for which the family might qualify.

Generalization probes (5 or 10 minute sessions) will be conducted regularly throughout the session, equating to less than an hour of parent commitment. Finally, the last week of treatment will consist of 8-15 hours of direct parent training in clinic and at home to ensure that treatment effects generalize to the home environment with the clients' parents. The amount of time required of the client and parent are the standards for typical clinical cases in the Center for Autism Spectrum Disorders.

We will use controlled, single-case experimental designs (multi-element, reversal) to conduct analyses and test clinical hypotheses for each child. We will interpret assessment and treatment results for each child using structured, visual inspection criteria developed and refined by our research team, which have demonstrated reliability, validity, and power to detect differences between test and control conditions with individual children (Fisher, Kelley, & Lomas, 2003; Hagopian et al., 1997). Any sessions recorded will only be obtained for data collection purposes and will be maintained up to a month following a given session on an encrypted UNMC server. After being maintained for up to a month following a given session, recordings will be erased.

Functional analysis. We will conduct a functional analysis to determine if the child meets inclusion criteria. Sessions will be 5 min in duration and the assessment should take about 1 week with 2-3 hour appointments 1-5 days a week. The functional analysis will take 1-3 weeks to complete (approximately 3 to 9, 2 to 3-hour study visits). The functional analysis will include at least three test conditions (social attention, demand, and alone/ignore) and one control condition (play). In accordance with best practice, we will include an additional test condition (tangible) if the caregiver reports or is observed to provide preferred tangible

items following destructive behavior. In the attention condition, the therapist will read while asking the child to play with a moderately preferred toy. If the child emits a destructive behavior, the therapist will deliver vocal (e.g., Stop that, you'll hurt yourself) and physical (e.g., rubs the child's head) attention. In the demand condition, the therapist will deliver non-preferred demands using sequential verbal, modeled, and physical prompts every 10 s. Compliance will produce praise, noncompliance will result in physical guidance and no praise, and destructive behavior will produce a 20-s break from demands. In the alone condition, the child will be alone in a treatment room without any toys or materials. If the child displays aggression, we will conduct an ignore condition instead of an alone condition, during which a therapist will be in the room but will not interact with or respond to child behavior. In the tangible condition, the therapist will give the child a highly preferred toy for 2 min prior to the session. The therapist will withdraw the toy at the start of the session and return it to the child for 20 s contingent on destructive behavior. In the control condition (play), the therapist will play with the child and deliver attention every 30 s for the absence of destructive behavior. Children showing destructive behavior maintained by social reinforcement (using the Hagopian et al. [1997] criteria), and who meet the other inclusion/exclusion criteria described above, will be invited to participate in this project.

Dependent variables and measurement. The primary dependent measure will be the rate of destructive behavior (aggression, property destruction, SIB) assessed via direct observation. Aggression will be defined as forceful pushing or striking others with body parts (e.g., pushing, hitting, kicking, head-butting), hitting others with objects or throwing objects at others, pinching, scratching, or biting. Property destruction will be defined as forceful banging, throwing, overturning, tearing or climbing on objects not made for that purpose. SIB will be defined as forceful striking, scratching, rubbing, poking or biting ones own body parts such that repetition of the behavior has or will cause bodily injury (e.g., head punching or banging, eye-poking).

Observation, blinding, reliability and validity of dependent and procedural-integrity measures. Trained observers will collect data on child destructive behavior and therapist (or caregiver) implementation of the assessment and treatment protocols to assess procedural integrity using DataPal®, software developed in our lab. A second observer will score at least one third of sessions independently to assess data accuracy (reliability). The second data collector will be blind to the projects research questions and hypotheses for one half (17%) of these sessions. For at least one third of sessions, observers will collect procedural-integrity data to determine whether the assessment and treatment protocols are implemented as planned. That is, we will collect data on whether therapists correctly implemented the planned antecedents, prompts, and consequences for each target response. We will then transform the data into a percentage-correct measure by dividing the number of correct therapist responses by the number of opportunities for a correct

response.

The reliability of direct-observation measures is typically established through measurement of inter-observer agreement. To calculate inter-observer agreement, sessions will be partitioned into successive, 10-s intervals (e.g., seconds 0-9, 10-19, 20-29). In each 10-s interval, we will determine whether the observers agreed or disagreed on the frequency of each target behavior. An exact agreement will be defined as both observers recording the same frequency of a target behavior in a given 10-s interval. We then calculate the percentage of exact agreements per session. Inter-observer agreement in our program averages above 90%, and observers undergo retraining if agreement levels fall below 80% for 3 consecutive sessions.

We recently completed the first calibration study to determine the accuracy of continuous recording of direct-observation measures of behavior (Mudford, Zeleny, Fisher, Klum, & Owen, 2011). In this study, five novice and five experienced observers recorded response samples on laptop computers with a priori determined response rates ranging from 0 to 8 responses per minute, which covered the range of 90% of the data sets published in the *Journal of Applied Behavior Analysis*. Results showed that the experienced observers recorded rates that were accurate to within ± 0.2 responses per minute (M = ± 0.12). Observers for this project will be comparably experienced and accurate.

In addition to its accuracy, direct-observation measures have several advantages over other assessments (e.g., rating scales) in terms of validity. Because target behaviors are directly measured, issues related to construct and predictive validity are not relevant (i.e., no need to predict or estimate a criterion variable when it is measured directly). Instead, direct-observation measures are judged primarily in terms of their face validity (e.g., the operational definition of aggression matches the everyday meaning of the term) and content validity (e.g., the topographies of destructive behavior measured in this project adequately cover the ones included in prior investigations; Nunnally, 1978). We developed the current definitions of destructive behavior based on recommendations of an NIH (1989) consensus conference and subsequent reviews of the literature.

Participant attrition and intent-to-treat principle. We will also follow the intent-to-treat principle and make every effort to follow up, complete assessments, and report on children who withdraw from the study. Over the last 5 years, we have retained over 95% of our patients (about one early withdrawal per year), thus we anticipate very low attrition and conservatively expect that at least 36 children will complete the project (about 9 per study).

Baseline. The baseline will be identical to the functional-analysis condition associated with the highest levels of destructive behavior (e.g., the attention condition for

attention-reinforced destructive behavior). To obtain stable rates of destructive behavior, data collection will continue for at least five sessions until the data meet the following stability criteria: (a) The standard deviation of the baseline will be no greater than 50% of its mean (e.g., *M* = 2, *SD* <= 0.8); (b) The trend for the baseline will be flat (slope <= | .05 |) or in the direction opposite the goal for treatment; and (c) No more than 20% of the baseline data points will be in the range targeted for treatment (i.e., 90% to 100% lower than the baseline mean).

FCT training. Once the above stability criteria have been reached in each condition, FCT training will begin in a separate stimulus. A card touch will be used as the FCR because it can be effectively prompted using gentle physical guidance regardless of the childs functioning level. FCT training will be identical to baseline, except that the therapist will (a) not provide reinforcement for destructive behavior (extinction; EXT) and (b) use gentle physical guidance to prompt the card-touch FCR once in every 30-s interval of the session starting with a 0-s prompt delay and progressing to 2-, 5-, 10-, and 20-s delays. The 0-s delay will be in effect for the first two sessions. Thereafter, we will lengthen the delay interval after the child emits prompted or independent FCRs in at least 90% of the 30-s intervals. The therapist will deliver the reinforcer that previously maintained destructive behavior (e.g., attention) for the remainder of each 30-s interval contingent on a prompted or independent FCR. FCT training will continue until the participant emits independent FCRs in at least 90% of the 30-s intervals for two consecutive sessions.

FCT. Once FCT training is completed, FCT will be introduced in the context in which the baseline was conducted. During FCT, the therapist will (a) discontinue reinforcement for destructive behavior (EXT) and (b) deliver reinforcement for the FCR until destructive behavior decreases by 90% (relative to the baseline mean) for two consecutive sessions.

B. Identify all procedures, interventions, evaluations and tests that are performed solely for research purposes.

Functional analyses and FCT are common clinical components in the assessment and treatment of problem behavior. These components would be implemented regardless of participation in this research study.

Although caregiver pretests and posttests are common components of clinical cases, we will not bill for these procedures. For behavioral interventions, we obtain authorizations from insurance companies that cover a span of time (e.g., a month, two months, four months) rather than authorization for specific tests (e.g., the pretest). To gain additional time with a client, we then have to request a reauthorization that often varies in time from the initial authorization. Thus, for the waitlist-control group, this would mean that obtaining authorization to conduct the pretest would use up one of the client's authorization periods

during the wait period despite the client not receiving services during this time, and reauthorization to bill for the posttest several months later. Therefore, we will consider all of the pretests and posttests as procedures for research and only bill for the clinical services received during the treatment portion of the admission.

C. Identify all procedures, interventions, evaluations and tests that are performed more frequently than they would be if the subject was not participating in the research.
The pretests and posttests are being conducted for research purposes and the additional pretest for the wait-list control group is occurring more frequently (i.e., twice) than what would occur typically in a clinical admission.

D. Describe briefly the statistical methods used to analyze the data.
Within-participant data analysis
We will use both structured visual inspection and appropriate statistical methods to analyze each participants single-case data sets. The visual-inspection procedures developed and validated by members of our team are highly reliable (IOA ≥ .95). In addition, we will use the Allison and Gorman (1993) regression procedure to calculate significance levels and effect sizes for single-case designs. Completing these analyses with individual children will allow us to determine, with a high degree of certainty, how many children responded in the predicted pattern.

Group statistics
To compare the changes from pretest to posttest, we will conduct analyses of group differences (FCT treatment vs. wait list) on the primary dependent variables using an analysis of covariance with the parent baseline pretest as the covariable and the parent baseline posttest the dependent variable.

CONFIDENTIALITY AND PRIVACY

12. Confidentiality and Privacy
A. Will research data be stored:
1) On a secure server at UNMC/TNMC/CH&MC/UNO?
Yes

2) On a local hard drive?
No

3) On a portable computer?
Yes

a) Is the portable computer encrypted and password protected?
Yes

4) On a flash drive?
No

5) In a database accessible through the internet?
No

6) In hard copy?
No

7) Other?
No

B. Will any of the following subject identifiers be recorded (at any time) in association with the research data?
Yes

1) Indicate the subject identifiers that will be recorded:
♦ Name
♦ Postal address information: street address, city, county, precinct, ZIP code
♦ All elements of dates (except year) related to an individual (e.g. birth, admission, discharge)
♦ Telephone numbers
Fax numbers
♦ Electronic mail addresses
Social Security numbers
♦ Medical Record numbers
♦ Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locators (URLs)
Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice prints
♦ Full face photographic images [and any comparable images]
No identifiers will be maintained

2) Will a unique subject identifying number, characteristic or code be used to protect the confidentiality of the data? This includes codes assigned by the investigator to link data to other identifiers like the subjectˆs name or medical record number?
Yes

a) Where will the key, that links the unique subject identification code to the subjectˆs name or other identifier, be stored?
A master list with participant numbers and names will be kept separate from other data in a locked cabinet in the principal investigators office.

3) What is the justification for recording the specific identifiers listed above?
Schedule appointments
Follow-up with subjects
♦ Other. Explain. Participants will be currently enrolled in the Severe Behavior Disorders Clinic in the Center for Autism Spectrum Disorders at the Munroe-Meyer Institute. The principal investigator will have access to the participant identifiers in order to follow up with subjects and schedule appointments.

4) How long will the subject identifiers be maintained in association with the research data?
Subject identifiers will be maintained for a minimum of seven years.

5) How will the research data be archived or destroyed when the data is no longer required?
Research data will be archived on an encrypted UNMC server. Video recordings for data collection purposes will be maintained up to a month following a given session before being deleted.

6) Will research data that contain subject identifiers be disclosed to any other investigators at UNMC, TNMC, UNO or CH&MC who is <u>not</u> listed in Section I of this application?
No

7) Will research data that contain subject identifiers be disclosed to any investigators <u>outside</u> of UNMC, TNMC, UNO or CH&MC?
No

8) Will research data that contain subject identifiers be disclosed to any commercial sponsor or contract research organization (CRO)?

No

9) Will research data that contain subject identifiers be disclosed to any other external organization or entity?
No

C. What provisions will be in place to protect the subject's privacy? Check all that apply.
♦ Obtaining consent in a private conference room or area
♦ Ensuring that only personnel listed on the IRB application Section I.3(A-E) are present during the consent process
♦ Ensuring that the fewest number of individuals possible are aware of the subject's participation in the research
♦ Ensuring that the research activities are performed in as private of a place as possible
Other. Explain.

D. Does this research involve data banking at UNMC, TNMC, UNO or CH&MC for future research that is not related to this study?
No

E. Does this research involve data banking by an outside organization (e.g. NCI Cooperative Group, pharmaceutical company) for future, unspecified research that are not integral to the current research?
No

RISK/BENEFIT ASSESSMENT

13. Potential Risks
What are the potential risks associated with each research procedure, intervention, evaluation and/or test? If data is available, estimate the probability that a given harm may occur and its potential reversibility.
There is a potential for child and therapist injury as a result of the childs problem behavior. Problem behavior such as aggression, property destruction, or self-injury may be occasioned by presenting difficult demands, restricting access to preferred items, or activities or restricting access to caregiver attention. All therapists participating in the study have received formal training on how to appropriately and safely block problem behavior in a manner that minimizes these risks. If the child engages in problem behavior that may result in injury to the therapist, the therapist will have the option to wear protective equipment during the assessment (e.g., arm guards, chest and shoulder pads, etc.). If the

child's problem behavior appears to escalate to unsafe levels, the session will be ended and clinically-approved measures will be implemented to ensure the safety of the child. In the seven years we have served this population at MMI no children have sustained injuries that have required medical attention.

While completing questionnaires, such as the Parental Stress Index, some of the questions may make caregivers uncomfortable. We will inform caregivers that they are free to terminate the questionnaires or the study at any point and still receive services through our Severe Behavior Disorders clinic.

14. Risk Classification
What is the overall risk classification of the research?
Minimal risk
♦ Greater than minimal risk

15. Minimization of Risk
A. Will the research utilize procedures that would already be performed on the subjects even if they chose not to participate in the research?
Yes

Describe the procedures.
Functional analyses and FCT are best practice for identifying the function of socially maintained destructive behavior and developing treatment based upon the target function.

B. Describe how the subjects of the research will be monitored by the investigators and other research personnel to ensure their safety.
Participants will have the investigators contact information if any situation occurs in which they are concerned. Additionally, if something happens in the home and the childs destructive behavior escalates, the caregivers are instructed to proceed as they typically would in contacting the police for immediate help. Also, if anyone sustains concerning injuries outside of the clinic hours, the caregivers will be instructed to contact an urgent care or emergency care facility, and follow up with the investigators the following day. Additionally, weekly meetings will be scheduled to address any caregiver concerns.

C. Describe the process by which the PI will be informed and how the PI, in turn, will inform other research staff about events concerning subject safety (including (a) interim results; (b) unanticipated problems involving risks to subjects or others; (c) noncompliance; (d) complaints).
1) At UNMC/TNMC/CH&MC and/or UNO (check all that apply)

Not applicable. The PI is the only person listed in Section I of the IRB Application.
♦ By email or campus mail (for events which do not constitute immediate subject safety hazards)
♦ By phone
♦ By in-person meeting
Other. Explain.

2) At external study sites under the oversight of the Joint Pediatric IRB as applicable (check all that apply)
By email or mail (for events which do not constitute immediate subject safety hazards)
By phone
By in-person meeting or teleconference
♦ Other. Explain. The current investigation will not occur at external sites.

D. Describe the auditing plan for research conducted:
1) Within the Organization (UNMC, TNMC, UNO or CH&MC), identify who will conduct the audits and specify the audit frequency..
All study personnel will conduct ongoing review of compliance with the protocol. Any violations of the protocol will be immediately reported to the Principal Investigator and the IRB. All study personnel will also conduct a comprehensive retrospective review of compliance with the protocol at the completion of each cohort (for a total of 5 comprehensive retrospective reviews of compliance with the protocol). Any violations of the protocol will be immediately reported to the Principal Investigator and the IRB.

2) At external study sites under the oversight of the Joint Pediatric IRB, identify who will conduct the audits and specify the audit frequency.
The current investigation will not occur at external sites.

E. Describe the data monitoring plan.
1) Who will perform the ongoing data and safety analysis?
The primary investigator and treatment team will meet on a daily basis to review the data and the safety of participants.

2) What is the frequency of data analysis?
The primary investigator will graph the data for all participants daily.

F. Describe the specific criteria by which the investigator would withdraw individual subjects from the research.
If the child exhibits severe problem behavior causing bodily damage to themselves or

others, the investigators will discuss continued participation in the study with the childs parents and teachers. If participants continuously miss appointments without reasonable excuses (e.g., 2 consecutive unexplained absences) the parents will be warned that their participation in the study may be terminated.

G. Describe the specific criteria for halting or early termination of the study.
When unexpected problems are encountered (e.g., unexpected risk to the participants are observed), the research project will be halted and the participants continued participation in the study will be discussed with his/her legal guardian(s).

16. Potential Benefits to the Subject
Are there potential benefits to the subjects that may reasonably be expected from participation in the research?
Yes

Describe.
Participants will receive treatment of destructive behavior and teaching of functional communication skills.

17. Potential Benefits to Society
What are the anticipated benefits (i.e., value) to society that may reasonably be expected to result from this research?
The results of the current investigation may extend the literature on the effectiveness of FCT for individuals with severe destructive behavior by identifying the generality of FCT effectiveness.

18. Alternatives to Participation
Are there any reasonably available alternatives in the non-research context which would have the potential for providing the same benefits to subjects?
Not applicable. There are no direct benefits to subjects; the alternative is to not participate in the research.
♦ Yes. Describe: The parents of potential participants will be informed that they are free to choose whether or not to participate in the current study. Participants will have the opportunity to receive services from the Munroe-Meyer Institute or from other facilities, regardless of their participation in this study. Parents of participants assigned to the waitlist control condition will be given a packet of information regarding local intervention services outside of Munroe-Meyer Institute^s Center for Autism Spectrum Disorders.
No. Explain:

FINANCIAL OBLIGATIONS AND COMPENSATION

19. Financial Obligations of the Subject
Are there any other financial obligations that the parent(s)/guardians of the subject will incur as a result of participating in the study (e.g. travel expenses, meals, supplies)?
Yes

Provide additional detail and justification for increased financial obligations to the parent(s)/guardian(s) of the subject.
Routine clinical services can be billed to the subject's insurance company. No procedures conducted solely for research purposes will be billed to insurance. The parent/caregiver will be responsible for all insurance deductibles as they relate to routine clinical services.

20. Compensation to the Subject for Participation
Will the subject and/or their parent(s)/guardian(s) receive any compensation for participation?
No

PRIOR REVIEW

21. Prior IRB Review
A. Has this study (or one substantially similar) been previously submitted to the Joint Pediatric IRB (or the UNMC IRB) and then withdrawn by the investigator for any reason?
No

B. To the best of your knowledge, has this study (or one substantially similar) been considered by another IRB and not granted approval?
No

SUBJECT IDENTIFICATION & RECRUITMENT

22. Method of Subject Identification and Recruitment
A. Will prospective subjects be identified through initial contact by the investigator?
Yes

1) Identified through (check all that apply):
Previous research participants
Investigator maintained databases or registries

School records
Support groups
♦ Other. Explain. Prospective participants will be children that are currently on the Severe Behavior Program waiting list

2) Describe how the research staff has ethical access to the potential subjects?
The primary investigator and staff have professional relationships with the prospective participants.

B. Will prospective subjects make the initial contact with the research personnel to inquire about the study?
No

OBTAINMENT OF INFORMED CONSENT

23. Waiver or Alteration of Informed Consent
A. Is a waiver or alteration of consent requested for parent(s)/guardian(s) of child subjects or for adult subjects?
No

B. Is a waiver of child assent requested?
Yes

24. Waiver of a Signed Consent Form
Is a waiver of the requirement to obtain a signed consent form requested?
No

25. Process of Permission (Informed Consent) for Parent(s)/Guardian(s)
A. When will the parent(s)/guardian(s) of the prospective subject be approached relative to their child's actual participation in the study?
A primary or secondary investigator will contact the parents via telephone call to discuss their child's involvement in the study. If interested, the investigators will meet the parents/guardians in-person to discuss the purpose of the study. A brief description of the procedures will be provided.

B. Where will informed consent be obtained, and how will the environment be conducive to discussion and thoughtful consideration by the parent(s)/guardian(s)?
Informed consent will be obtained in a private conference room, allowing the parents/guardians to reflect on their child's participation in the study while in a quiet

environment.

C. Who will be involved in the process of consenting the parent(s)/guardian(s) about their child's participation in the study and what are their responsibilities?
Secondary investigators (Dr. Brian Greer, Dr. Cathleen Piazza, Dr. Amanda Zangrillo) or the following participating personnel (Ashley Fuhrman, Todd Owen, Adam Briggs, Daniel Mitteer, Billie Retzlaff, Lauren Phillips, Ryan Kimball, Kayla Randall, or Madeleine Keevy) will provide the parents/guardians with an overview of the study and the consent process. These investigators will ask questions to ensure that the caregivers understand the documents presented to them and will refer any of their concerns to the primary investigator, Dr. Wayne Fisher.

D. How much time will be allotted to the process of consent?
Parents/guardians will be allowed as much time as they would like to review the clinical services that we plan to provide and will be encouraged to take the information home to make their decisions.

E. How will the process of consent be structured for parent(s)/ guardian(s) who are likely to be more vulnerable to coercion or undue influence?
We will provide the option for parents to include family, friends, an advocate, or other confidants. Investigators will question the parents or guardians about each sections of the consent form to ensure they understand.

F. Will non-English speaking subjects be enrolled in this research and/or will non-English speaking parent(s)/guardians be consenting for the prospective subject?
Yes

Explain how you will ensure that the language used in the consent process and consent form is understandable to the subjects and/or parent(s)/guardian(s).
An interpreter will be used to obtain consent from non-English speaking participants. All printed documents will be translated and will be submitted for review and approval from the IRB prior to utilization.

G. How will it be determined that the parent(s)/guardian(s) understood the information presented?
Parents/guardians will be asked questions about each section of the consent form to ensure all elements are understood. Parents/guardians also will be encouraged to ask any questions they may have throughout the process.

H. Will there be a formal process of on-going re-consent (over and above re-consent associated with changes in protocol)?
No

28. Documentation of Consent and Assent
List who will sign the consent form as the "Person Obtaining Consent".
Brown, Katherine R

Fisher, Wayne W

Fuhrman, Ashley Marie

Greer, Brian D

Keevy, Madeleine Diane

Kimball, Ryan Taylor

Mitteer, Daniel Robert

Owen, Todd M

Phillips, Lauren Amanda

Piazza, Cathleen C

Randall, Kayla Rechelle

Retzlaff, Billie Jean

Zangrillo, Amanda N

29. Consent Forms and Study Information Sheets
Indicate the type of consent forms and study information sheets to be used in this research.
♦ Parental/Guardian consent form
Youth Study Information Sheet
Child Study Information Sheet
Screening consent form

Addendum consent form
Adult consent form
Other:

30. Information Purposely Withheld
Will any information be purposely withheld from the parent(s)/guardian(s) of the subject or the subject during the research or after completion of the research?
No

RESOURCES

30. Describe the resources available to safely conduct this study at <u>each</u> sites specified in Section I.7.
Departmental funds will be used for this research. These funds will be used to obtain materials needed to complete the study (e.g., leisure items, instructional materials, functional communication cards). Sessions will be conducted in a private session room in the Severe Behavior Disorders clinic at Munroe-Meyer Institute. All data will be stored on a secure drive accessible only by employees at the Center for Autism Spectrum Disorders at the Munroe-Meyer Institute. The primary investigator and staff will meet on a daily basis to review the data and discuss any unanticipated problems that arise. If problems arise, the primary investigator and staff will meet immediately to discuss possible solutions.

LITERATURE REVIEW

31. References
Provide a full listing of the key references cited in the background (Section II.3). The references should clearly support the stated purpose of the study.
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Nunnally, J. C. (1978). *Psychometric theory.* New York, NY: McGraw-Hill.

Tiger, J. H., Hanley, G. P., & Bruzek, J. (2008). Functional communication training: A review and practical guide. *Behavior Analysis in Practice, 1,*16-23.

SECTION III

SUBMISSION DEADLINE

A. Full Board Review:
The IRB meets monthly, on the fourth Tuesday of the month. No more than 15 applications (i.e., initial review of a new study, re-review of a tabled study) will be reviewed at each meeting. All reviews are performed on a first-come first-served basis. The IRB meeting schedule and deadline dates can be found on the IRB website at www.unmc.edu/irb.

B. Expedited Review
Applications that qualify for expedited review have no submission deadline and can be reviewed independent of the IRB meeting schedule. Please call the Office of Regulatory Affairs for assistance in determining if your study meets the requirements for expedited review.

SUBMISSION CHECKLIST

Check all that apply.
Subject recruitment material
Performance site approval for all non-UNMC, TNMC, UNO and CH&MC sites
Copy of all questionnaires, surveys, assessment tools, and other relevant materials
Detailed protocol
Grant Application
IRB Review Fee Form for all commercially sponsored research projects.
UNMC Disclosure of Potential Conflict of Interest Form for the Principal Investigator if a financial interest has been declared in Section I.10.
UNMC Disclosure of Potential Conflict of Interest Form for any responsible personnel with a financial interest declared in Section I.10.
Other
♦ No attachments

ADDITIONAL REVIEW REQUIREMENTS

Final IRB approval and release of studies is contingent upon approval by the following UNMC committees or departments. Check the appropriate boxes:
UNMC Eppley Cancer Center Scientific Review Committee (SRC): Review by the SRC is required for all protocols involving cancer patients.
Sponsored Programs Administration (SPA)/Office of Regulatory Affairs: For

commercial sponsored studies, the consent form and contract will be compared for consistency. Final IRB approval and release is contingent upon completion of a signed contract for all commercially sponsored research.

Conflict of Interest Committee (COIC) All responsible personnel listed in I.3A-E of the IRB application (i.e., PI, Secondary Investigator, Participating Personnel, and Coordinator(s)) must disclose **any** financial interest in the research (see Section I.10 of this application). Data and Administrative Personnel are exempt. The COIC will review any financial interest which is classified as significant.

Investigational Device Review Committee (IDRC): Review by the IDRC is required for all protocols involving the use of investigational or marketed devices.

♦ **No Additional Reviews Required**

ADDENDUM L
Waiver or Alteration of Child Assent

Title of Protocol
Treatment of severe destructive behavior: A randomized clinical trial of functional communication training versus wait-list control

Principal Investigator
Fisher, Wayne W - MMI Ctr for Autism Spec Disord - 402-559-8863 - wfisher@unmc.edu

Waiver or Alteration of Child Assent

1. Is waiver or alteration of assent being requested because the children lack capacity to provide assent. [45 CFR 46.408(a) and 21 CFR 50.55(c)(1)]?
Yes

2. Is waiver or alteration of assent being requested because there is direct benefit to the children which is only available in the context of the research. [45 CFR 46.408(a) and 21CFR 50.55(c)(2)]?
No

3. Is waiver or alteration of assent being requested because obtaining assent is impracticable, the research is no more than minimal risk and the rights and welfare of the subject will not be adversely affected. [45 CFR 116(d) and 21 CFR 50.55(d)]?
No

A. Children that Lack Capacity to Provide Assent

Explain why the capability of some or all of the children is so limited that they cannot assent to participate in research. [45 CFR 46.408(a) and 21 CFR 50.55(c)(1)]
All children will be currently enrolled in the Severe Behavior Disorders clinic at the Munroe-Meyer Institute or on the wait list. Many of the children who attend these clinics have cognitive impairments and participants for this study will have limited communication skills. Thus, the children in the current study will lack the capacity to assent to participation.

ADDENDUM Y
Research Involving Adults as Subjects Participating in a Pediatric Trial

Title of Protocol
Treatment of severe destructive behavior: A randomized clinical trial of functional communication training versus wait-list control

Principal Investigator
Fisher, Wayne W - MMI Ctr for Autism Spec Disord - 402-559-8863 - wfisher@unmc.edu

Waiver of Alteration of Informed Consent
Is a waiver of alteration of consent requested?
No

1. Capacity to Consent
a. At the time of initial consent, will all subjects have the capacity to give informed consent?
Yes

b. Is there a reasonable likelihood that some subjects may lose the capacity to continue to provide informed consent during the course of the study?
No

2. Process of Informed Consent for Competent Adult Subjects
a. When will the prospective subject be approached relative to their actual participation in the study?
The caregivers of the children participants will approached several weeks prior to their actual participation in the study.

b. What is the location where informed consent will be obtained, and how will the environment be conducive to discussion and thoughtful consideration?
Informed consent will be obtained in a private conference room, allowing the parents/guardians to reflect on their participation in the study while in a quiet environment.

c. Who will be involved in the process of consent and what are their responsibilities?
Secondary investigators (Dr. Piazza or Dr. Greer) or participating personnel (Ashley Niebauer, Daniel Mitteer, Valdeep Saini, Katherine Lichtblau, Patrick Romani, Todd Owen

or Andresa De Souza) will provide the parents/guardians with an overview of the study and the consent process. These investigators will ask questions to ensure that the caregivers understand the documents presented to them and will refer any of their concerns to the primary investigator, Dr. Wayne Fisher.

d. How much time will be allotted to the process of consent?
Parents/guardians will be allowed as much time as they would like to review the information that we willprovide and will be encouraged to take the information home to make their decisions.

e. How will the process of consent be structured for subjects who are likely to be more vulnerable to coercion or undue influence?
We will provide the option for parents to include family, friends, an advocate, or other confidants. Investigators will question the parents or guardians about each section of the consent form to ensure they understand.

f. Will non-English speaking subjects be enrolled in this research?
Yes

Explain how will you ensure that the language used in the consent process and consent form is understandable to the subjects.
While most caregivers whose children attend our clinic are English-speaking, a UNMC interpreter will be provided during all interactions between research personnel and non-English speaking caregivers. The research personnel will use the same level of detail with non-English speaking caregivers via the translator as they would with English speaking caregivers who are consented.

g. How will it be determined that the subject understood the information presented?
Parents/guardians will be asked questions about each section of the consent form to ensure all elements are understood. Parents/guardians also will be encouraged to ask any questions they may have throughout the process.

h. Will there be a formal process of *on-going* re-consent (over and above re-consent associated with changes in protocol)?
No

3. Consent and Assent Forms
Indicate the type of consent forms and/or study information sheets to be used in this research:

Adult consent form
Legally authorized representative (LAR) consent form
Adult study information sheet
Screening consent form
Addendum consent form
♦ Other. Explain. Parental consent form