**IRB Proposal Synopsis:**

**Clinic for Autism Research, Evaluation, and Support (CARES) Research Project**

**Co-PIs**:

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**OVERVIEW**

We are seeking IRB approval to use the data that is collected by the Clinic for Autism Research, Evaluation, and Support (CARES) in research. CARES is a Texas State University-based clinic established by the College of Education. The clinic is located in the Education Building. CARES offers diagnostic services and intensive educational and recreational services. If approved, the data that is generated from the assessments, motor/recreation program, and Applied Behavior Analysis program would be able to be used for research purposes.

CARES clients and their families will be asked if the data that will result from the services they receive from CARES can be used for research purposes. The decision to participate in research will not affect the nature of the services delivered and services will not be denied to a family based upon their decision to be involved in research.

**1. Source of Potential Subjects**:

CARES clients may self-refer or be referred by their legal guardians, medical health care providers, and/or school districts for assessment and treatment services. The number of individuals that will ultimately participate in research will depend on the number of referrals and the number who give informed consent/assent. CARES provides services to:

1. Individuals with a diagnosed Autism Spectrum Disorder (ASD)
2. Individuals suspected of having an ASD who are not diagnosed
3. Individuals diagnosed with (or suspected to have) other intellectual or developmental disabilities (e.g., Downs Syndrome & Cerebral Palsy).
4. Individuals with (or suspected to have) emotional and/or behavioral disorders
5. Individuals who are typically developing

**2. Procedures for Recruitment and Informed Consent:**

*Recruitment and Advertising:*

The CARES clinic is advertised to the public via the CARES website (<http://cares.education.txstate.edu/>), brochure, and flyer. The brochure and flyer can be downloaded from the website for review.

*Informed Consent and Assent Requirements:*

CARES data will only be used for research purposes when the following conditions are met:

1. The individual receiving services must provide informed consent/assent (see attached Child Assent form and Adult Consent form). If the individual is not able to provide informed consent/assent due to a severe/profound intellectual disability then consent from a legal guardian will be considered sufficient.
2. In addition to child assent, if the individual is less than 18 years old, then a legal guardian must also provide informed consent (see attached Parent Consent form).

*Procedures for Obtaining Consent/Assent:*

After a potential participant is referred to CARES, a trained clinic coordinator and/or one of the CO-PIs listed above, will explain the clinical process to the potential participant, gather preliminary intake data, and offer the individual (or their guardian) the option to be involved in research. Individuals will be given the appropriate CARES informed consent/assent form and given the opportunity to ask questions regarding the research. Individuals and/or their guardians will be asked to sign the consent/assent form if they wish to allow their data to be used in research.

**3. Description of Methodology and Procedures:**

This section of the IRB proposal is divided in three parts. Part 1 lists procedures, assessment protocol, and examples of potential research questions related to the CARES assessment services. Part 2 lists procedures and example research questions related to the sensory-motor services. Part 3 lists the procedures, assessments, interventions, and example research questions related to the Applied Behavior Analysis Services.

***Part 1: Methodology and Procedures for Assessment Services***

Intake for clinic assessment will be conducted over the phone. Families will be provided with a packet of questionnaires. This packet will need to be completed and returned when the parents return to the clinic for a parent interview. The parents will also be provided with a teacher packet of questionnaires to give to the child’s teachers/ care providers when appropriate. Completion of the parent questionnaires may take 2 to 4 hours. Completion of the teacher questionnaires may take up to 2 hours. The face-to-face parent interview may take from 2 to 6 hours to complete. The assessment sessions with the child/client will take between 3 to 7 hours depending on the assessment battery administered and age of the child/client. The assessment battery will be selected based on the child’s age and/or language level. A series of norm and criterion referenced tests will be administered to assess the following developmental areas: cognition, adaptive behaviors, executive functioning, motor, memory, interpersonal communication and relationships, basic achievement skills and repetitive and restrictive behaviors. Each of these assessments is commonly administered to individuals suspected of having developmental disabilities and are widely considered useful, appropriate, and safe. If the child is diagnosed with a hearing loss, he/she will be excluded from the research study. The entire assessment battery can be conducted in 2 to 3 visits. A parent feedback session will be scheduled to discuss findings and recommendations resulting from the assessment battery (refer to the CARES Clinical & Research Form for an outline of the process and timelines). When appropriate, the child may be referred for the ABA and/or motor skills intervention services also provided by CARES (see corresponding sections below).

The following table summarizes the assessment techniques that are considered for each CARES evaluation. No child would receive all of these assessments. The specific battery each child receives is designed based on the individual referral question and the characteristics of the child.

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| **Instrument** | **Age Range (years)** | **Type of administration** |
| Autism Diagnostic Observation System (ADOS) | 1-6 to adult | Individual assessment of autism characteristics |
| Autism Diagnostic Interview- Revised (ADI-R) | 2-0 to adult | Parent interview related to autism characteristics |
| Psychoeducational Profile, 3rd Edition (PEP-3) | 6 mos to 7 years | Individual administration related to cognitive, language, motor and interaction characteristics related to autism |
| Childhood Autism Rating Scale, 2nd Ed. (CARS-2) | 2 to 19 | Rating scale completed by all clinicians working with the family |
| Gilliam Autism Rating Scale, 2nd Edition (GARS-2) | 3 to 22 | Parent and teacher rating |
| Gilliam Asperger’s Rating Scale | 3 to 22 | Parent and teacher rating |
| Social Communication Scale | Over 4 | Parent and teacher rating |
| Social Reciprocity Scale | 4 to 18 | Parent and teacher rating |
| Woodcock Johnson Psychoeducational Battery | 2-6 to 90 | Individual cognitive and academic test |
| Differential Ability Scales, Second Edition | 2-6 to 21-11 | Individual cognitive test |
| Wechsler Abbreviated Scales of Intelligence | 6 to 89 | Individual cognitive test |
| Kaufman Assessment Battery for Children, 2nd Edition | 3 to 18 | Individual cognitive test |
| Wechsler Nonverbal Scales of Intelligence | 4 to 12-11 | Individual cognitive test |
| Vineland Adaptive Behavior Scales, 2nd Edition | Birth - 90 | Parent and teacher rating |
| Brief Rating of Individual Executive Functioning | 2- to 18 | Parent and teacher rating  Self rating |
| Dean Woodcock Neuropsychological Battery | 4 to adult | Individual test of neuropsychological functioning |
| Behavior Rating Scales for Children, 2nd Edition | 2-0 to 21-11 | Parent and teacher rating  Self Rating |
| Human Figure Drawing | All | Individual projective test |
| Projective Drawings | All | Individual projective test |
| Haak Sentence Completion | All | Individual projective test |
| Roberts Apperception Test | All | Individual projective test |
| Thematic Apperception Test | Late childhood and older | Individual projective test |
| Rorschach Inkblot Test | 5 to adult | Individual projective test |

Possible assessment related research questions that might be addressed using this data include the efficacy and accuracy of diagnostic protocols and the establishment of connections of specific early developmental assessment data that is related to later outcomes and diagnosis. For example: 1) For children identified by the Autism Diagnostic Observation Schedule (ADOS) as on the spectrum, what is the implication for measuring cognitive functioning? 2) How can measures of executive functioning impact intervention planning for individuals with autism spectrum disorders? 3) How can case studies with extensive assessment batteries including many different measures inform intervention and what are the implications for assessment in different settings? 4) What are the differential diagnosis considerations with other disorders that share symptoms with autism spectrum disorders, such as Smith McGinnis syndrome, Attention Deficit Hyperactivity Disorder, Central Auditory Processing Disorder, etc.

When participants or their guardians provide consent they will be giving permission for their data to be used to address any research question listed above or any similar research question. The informed consent forms will not list specific research questions to be addressed, but will make the open-ended nature of the potential use of this data clear.

***Part 2: Methodology and Procedures for Sensory-Motor Services***

One of the earliest views of the behavioral profile of ASD stressed the intactness of early motor development. Within a decade, however, there was growing recognition that individuals with ASD experience motor difficulties. Unusual gait, including slower pace, decreased step length, increased knee flexion, and unusual upper extremity positions during walking, were described in individuals with autism (Vilensky, Damasio, & Maurer, 1981). Several studies have now found evidence of motor delays and sensorimotor impairments in children with autism when they are compared with typical developing children (Jansiewicz, et al., 2006; Kern et al., 2006; Minshew, Sung, Jones, & Furman, 2004). Sensory-Motor difficulties are now becoming one of the common sources of referral for physical and occupational therapy.

The purpose of the assessment protocol below is to examine the fundamental sensory - motor skill of children with ASD, and to compare their performances with the norms reported by Ulrich (2000) for the Test of Gross Motor Development (TGMD-2), and Henderson (2007)’s Movement Assessment Battery for Children -2 (Movement ABC-2) and Dunn (1999)’s Sensory Profile. The success of their interactions on the playground and in physical education may also be dependent upon how well they interact with various sensory environments and are able to perform fundamental fine and gross motor skills.

Data collection instruments will include:

1. *Test of Gross Motor Development -2 (TGMD-2)* – The TGMD-2 (Ulrich, 2000) is a norm and criterion-referenced test that assesses the gross motor ability of children 3-10 years. It measures performance of 12 fundamental motor skills. Two subscales (consisting of 6 motor skills) make up the instrument: the locomotor subscale (run, gallop, hop, leap, jump, and slide) and the object control subscale (strike, dribble, catch, kick, throw, and roll). The TGMD-2 has shown evidence of validity and reliability among children. Subtest standard scores and percentile can be calculated to determine a child’s motor skill comparing to the standardized norms.
2. *Movement Assessment Battery -2 (Movement ABC-2) –* The Movement ABC -2 (Henderson & Sugden, 2007)contains 8 fundamental motor tasks for each of 3 age ranges (3-6 years; 7-10 years and 11-16 years) in three areas: Manual Dexterity, Ball Skills and Static and Dynamic Balance. The Movement ABC-2 is an evaluative tool that can be used to identify children who are significantly behind their peers in motor development, assist in planning an intervention program in either a school or clinical setting, measure change as a result of intervention, or serve as a measurement instrument in research involving motor development. Each task’s percentile can be calculated to determine a child’s motor skill comparing to the standardized norms.
3. *Modified Sensory Profile (MSP)* – The modified Sensory Profile is a 38-question caregiver-completed profile that reports the frequency of the child’s response to various sensory experiences (Dunn, 1999). Caregivers are asked to answer questions which best describe the frequency with which the child engages in the listed behaviors. Choices are: never (five points); seldom (four points); occasionally (three points); frequently (two points); and always (one point). The Sensory Profile is recommended by therapists that work with children with ASD because the Sensory Profile accurately reflects the person’s sensory processing and measures threshold.
4. *Parental Interview* - the parents will be asked to complete a 38-item questionnaire. A sample question is: Does your child shy away from loud noises? It should take about 10 minutes to complete all items. The child will be asked to complete a set of 12 gross motor skills (run, gallop, hop, leap, jump, slide, strike, dribble, catch, kick, throw, and roll) in the gymnasium at a convenient time for them. The gross motor skill assessment will take about 15-30 minutes for the child to complete. After gross motor assessment, the child will take a 30 minutes break, and then he/she will be asked to perform 8 fundamental motor tasks in the areas of Manual Dexterity, Ball Skills and Static and Dynamic Balance which will take about 30-50 minutes to complete. Participants will be videotaped during the assessments to ensure the sessions follow all the guidelines of the study so their safety is always maintained. All children involved will be closely supervised by an adult to minimize any risks for injury.

Possible assessment related research questions that might be addressed using this data include questions related to motor development in ASD, improvement in motor skills following exercise programs, and other similar questions.

***Part 3: Methodology and Procedures for Applied Behavior Analysis Treatments***

A considerable amount of research has focused on developing interventions for children with ASD. The most successful intervention approach for reducing problem behavior, improving social interactions, and teaching communication/self-help skills to children with ASD is Applied Behavior Analysis (ABA). ABA strategies can be implemented using a variety of different procedures or intervention packages. Four common ABA intervention packages that will be provided by the CARES clinic are Picture Exchange Communication System (PECS), Pivotal Response Training (PRT), Discrete Trail Training (DTT), and Functional Communication Training (FCT). Each of these interventions has been demonstrated to be effective with children with ASD in previous research. However, questions regarding the relative effectiveness of interventions (i.e., what intervention works best with what population) and how best to teach caregivers and therapists to implement these interventions remain unanswered and will be addressed in this project. Additionally, questions regarding ways to improve the efficiency of these interventions based upon individual participant characteristics will also be addressed. All modifications of these interventions will be done by changing intervention parameters in a way consistent with previous research (e.g., adjusting the value or frequency of reinforcement, changing the language used to deliver interventions, or utilizing various prompting strategies) and in a manner consistent with the participants’ treatment goals. Therefore, the services received by the participant will be the same regardless of whether the data is used for research purposes.

Children referred to CARES for ABA-based intervention services may have undergone the battery of assessments described above already. However, individuals receiving ABA services may also receive a Functional Behavioral Assessment (FBA), Functional Interview, Functional Analysis, Preference Assessment, or some other similar assessment commonly used in the creation of ABA intervention programs. The purpose and procedures for these assessments are described below:

*1. Functional Behavioral Assessment (FBA)*: The FBA process is a central component of the Individuals with disabilities Education Act (IDEA, 2004) and is very common in schools serving individuals with developmental disabilities. The FBA process involves a series of observations conducted in the child’s natural environment (e.g., home or school). FBAs are intended to identify changes in the child’s environment before and after the occurrence of problem behavior. By noting environmental changes that occur contingent upon problem behavior it is possible to form a hypothesis regarding the reason why problem behavior occurs. FBAs consist of between 1 and 20 observations lasting between 30min and 1 hour each. During the observation the observer does not interact with the individual being observed and takes notes regarding the behavior.

*2. Questions About Behavioral Function (QABF)*: The QABF is an empirically derived and psychometrically sound behavior rating scale given to the caregivers (e.g., parents or teachers) used to assess problem behavior in individuals with ASD. The QABF consists of 25 questions and a copy of the QABF is attached to the IRB proposal.

*3. Functional Analysis (FA*): A FA is a common assessment conducted for the same purpose as the FBA (see above) that involves a systematic manipulation of environmental variables. For example, if it is hypothesized that a child may engage in problem behavior in order to escape or avoid academic demands then, in an FBA, we wait and observe when demands are made and note the correlation between the demand and occurrence of problem behavior. However, in an FA instead of waiting for the academic demand to occur naturally, we give the demand for the sole purpose of assessing the occurrence of problem behavior. If problem behavior occurs then the demand is withdrawn. By noting the occurrence and non-occurrence of problem behavior when demands are intentionally placed and withdrawn, the FA allows for a demonstration of cause and effect, while the FBA allows only for a demonstration of correlation. In addition demands being systematically given and withdrawn, attention and preferred items may also be added or withdrawn during assessment conditions. FA’s are typical involve between 5 and 10 session with each session lasting approximately 30 min and may be conducted in the natural environment or within a controlled clinical setting. Because FAs are individualized to the context and individual being assessed, a standard protocol can not be given a priori.

*Preference Assessments:* A preference assessment is a formal procedure used to identify stimuli that may act as reinforcers. During a preference assessment a child is given multiple items (toys, food, etc) that the parent believes the child likes. Data is collected on how often a child selects one stimulus over another and/or on how long a child engages with a particular item. This data is used to identify the most preferred item.

Based upon the assessments described above, ABA intervention will be individualized for each participant. ABA interventions will be delivered in sessions lasting no longer than three hours each. The number of sessions required will depend on the skill being taught and the child’s rate of acquisition. Sessions will be implemented by graduate students under the supervision of a clinical director or one of the Co-PIs listed above. Below is a description of each of the intervention packages (independent variables) that may be used.

*1. Picture Exchange Communication System:* PECS involves teaching the child with ASD to communicate via handing their partner a picture or symbol card which depicts the child’s communicative intent. For example, if the child desires candy then the child hands a picture of candy to a person likely to provide candy. When instructing a child to use PECS, the instructor physically prompts the child to engage in picture exchange and blocks the child from obtaining the desired reinforcer via another behavior (e.g., reaching for candy directly). Over time, these physical prompts are systematically faded and more complex exchanges (i.e., multiple cards forming a sentence) are taught. In addition to increases in picture exchange-based communicative acts, PECS has also been shown to increase spoken communication in children with ASD.

*2. Pivotal Response Training*: PRT targets verbal behavior as opposed to picture exchange. For example, if the child desires candy then the therapist would verbally model the request by saying “candy” until the child imitates. If the child is not able to articulate “candy” correctly then a verbal approximation is prompted and is reinforced (e.g., “ca”). Over time, prompts are faded until spontaneous verbal communication occurs. PRT typically occurs during a “play” session in which the therapist has given the child several preferred toys. The therapist then plays with the child while trying to prompt communication.

*3. Discrete Trail Training*: DTT is an intensive intervention protocol that involves multiple learning trials. Each learning trial has 5 parts. 1. Cue: (discriminative stimulus) in which the therapist presents a clear instruction or question (e.g., “touch the red doll” or “what is your name?”). 2. Prompt: Immediately following the cue, the therapist assists the child to ensure the child provides the correct response or answer. This may be done by modeling the correct response, guiding the child’s hand, or pointing to the correct answer. Overtime, as the child becomes more proficient, the prompts are reduced to allow the child to independently answer the questions. 3. Response: The child will correctly or incorrectly respond to the therapists cue. 4. Consequence: If the response is correct then the therapists rewards (reinforces) the answer by giving the child something the child likes (e.g., praise, small piece of fruit, sticker, etc).If the answer is incorrect then no reinforcer is given, the therapist says, “no” and the instruction is presented again followed by a more helpful prompt. 5: Intertrial Interval: The therapist pauses for 1 to 3 seconds between learning trials. This process is repeated until the child masters a particular skill.

*4. Functional Communication Training:* FCT is designed to reduce problem behavior by teaching a new communicative behavior to replace the problem behavior. The first step in FCT is to determine the problem behavior’s function (reinforcing consequence) using one or more of the assessments described above. Second, a communicative replacement behavior that is easier to perform and more socially appropriate is selected. For example, if a child tantrums in order to obtain attention in the classroom, then the behavior of raising the hand maybe selected as the replacement behavior because raising a hand is a more socially appropriate behavior for asking for attention in most classrooms and is easier (i.e., requires less energy) than a tantrum. Third, the child is taught the replacement behavior using procedures similar to DTT and PRT (described above). Finally, the challenging behavior is ignored (i.e., placed on extinction) and the reinforcing consequence (in this case attention) is provided contingent only on the target behavior. For example, during FCT, tantrums would not result in any interaction with the teacher, but raising the hand would results in the delivery of attention from the teacher.

*Dependent Variables for ABA Interventions:* Depending on the unique needs of the children referred for services, one or more of the following dependent variables may be measured: a) changes in the occurrence of problem behavior, b) changes in academic skills, and/or c) changes in social or communication skills. Data collection methods used to assess change in these variables will include: counting or estimating the number of occurrences of problem behavior, appropriate behavior, or social interactions (i.e., rate, time sampling, or frequency data), or changes in assessment results (using the assessments described above)

*Research Designs for ABA Interventions:* A series of single subject designs (SSD) will be used. SSD demonstrate experimental control within participants’ behavior changes as opposed to between groups of participants as in statistical group designs. SSD are the most commonly used research designs with the developmental disability population and when evaluating ABA interventions. SSDs allow for analysis of small numbers of participants and for individualization of independent and dependent variables for each participant. The specific SSD formats that may be utilized include: multiple baselines, multi-element, alternating treatments, and ABAB designs.

If possible statistical group designs may be used if a sufficient number of participants are ever receiving services from CARES at a given time. In the event a group design becomes possible, all groups will receive intervention. This will be accomplished by either assessing the relative efficacy of two research-based interventions (e.g., a PRT group compared to a PECS group) or by providing intervention to a no treatment control group after the completion of the study.

**4. Potential Risks**:

The project proposed here posses no more than minimal risk. The assessments and treatments delivered by CARES are common research-based practices. The probability of harm or discomfort is not greater than risks encountered in daily life during the performance of routine school activities. It is important to note that the people receiving services will receive the same assessments and treatments regardless of whether or not the resulting data is used in research. Due to this, the largest additional risk presented by the addition of research, is the increased potential for a breach of confidentiality.

**5. Procedures for Protecting and Minimizing Risk**:

In order to reduce the risk of a breach in confidentiality several protective actions will be taken. All documents containing personal information such as the participant’s name, medical information (e.g., diagnosis), educational information (e.g., academic grades), assessment results, and results of the research will be kept within locked file cabinets in locked CARES’ offices or in the office of one of the project’s Co-PIs. Fake names will be used in all publications and conference presentations. All files stored electronically will be kept on password protected computers on an encrypted hard drive in locked offices. Alternatively, electronic files may be stored on a portable flash drive that will be kept in a locked cabinet in a locked office. Finally, documents with personal information for each participant will be destroyed by shredding within 10 years of project completion. Any breach of confidentiality will be immediately reported to the participant’s guardian and the IRB.

**6. Potential Benefits**:

Participants in this study will likely benefit from the provision of thorough and accurate assessment and from improved skills and behavior resulting from the research-based ABA interventions. Legal guardians, Texas State University (TSU) students, and school personnel may learn new strategies for influencing problem behavior and teaching academic, social, and/or communication skills to children with ASD. Finally, the global ASD population may benefit from the dissemination of research findings.

**7. Compensation**:

CARES charges fees for assessment and intervention services. These fees range from $1.00 dollars per hour to $1,000 dollars for the assessment battery. These fees will be the same regardless of a client’s decision to be involved in research.

**8. Risk Benefit Analysis**:

The high likelihood that participants will benefit from accurate assessment and from receiving research-based ABA interventions compared to the low likelihood of a breach of confidentiality suggests this project is of substantially more potential benefit than potential harm.

**9. Sites and Agencies Involved**:

Not Applicable

**10. Texas State Students:**

No TSU student will be acting as a Co-PI. However, students enrolled in courses connected with CARES may be involved as data collectors, assessment implementers, and therapists. Students performing these actions will be under the supervision of one of the listed Co-PIs. Students may also be co-authors on resulting publications.

**11. Student Projects:**

Texas State students will be receiving training on how to implement the assessments and interventions used in the clinic. As such TSU students will be observing clients, implementing procedures, collecting data, and participating in other daily clinical operations (See above).

**12. Previous IRB:**

A similar IRB was approved by the Texas State University IRB board in 2007 (**IRB Protocol #2007-43033)**. In the previous IRB, diagnostic and assessment services and research procedures were nearly identical, but ABA-based intervention services were not covered. Additionally, this current IRB has additional faculty acting as Co-PIs.

**13. Access to Results:**

The following faculty will conduct the various research studies and therefore will have access to the data. Results may also be presented for publication or presentation. Results will be made available to the families and clients receiving services upon there request.

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