Institutional Review Board Protocol
For
Conduct of Research Involving Human Subjects

PROJECT

Project Title: A Modeling and Shaping Approach to Increase Food Related Responses for Children with Autism Spectrum Disorder

Project Start Date: 10/01/2018 Project End Date: 05/01/2019

RESEARCHER(S)

Principal Investigator(s) Also referred to as PI(s) *First Name*	*Last Name*	Status (select one)	SCSU Email	Phone Number	IRB Training Completed	Training Date
Kelli	Check	○ faculty/staff ○ undergraduate ◉ graduate masters ○ graduate doctoral	kmcarlile@stcloudstate.edu	760-964-5629	☑ Yes	06/14/2017
		◉ faculty/staff ○ undergraduate ○ graduate masters ○ graduate doctoral			☐ Yes	
		○ faculty/staff ○ undergraduate ○ graduate masters ○ graduate doctoral			☐ Yes	

	First name	**Last name**
Faculty Mentor/Course Instructor (if Principal Investigator is a student):	Kimberly	Schulze

☑ Yes, ALL Principal Investigator(s) completed SCSU's required CITI IRB training, https://www.citiprogram.org/

If you collaborate with an individual from another institution, we may be able to use an Authorization Agreement with anther institution's IRB. Contact ResearchNow@stcloudstate.edu for more information.

SPONSORS

Is there external funding source(s) for this research project? ◉ No ○ Yes ○ Pending

Funding Agency/Sponsor: Account #:

PROTOCOL SUBMISSION CHECKLIST

To submit a complete packet to the IRB, INCLUDE all of the following:
☑ Complete, signed IRB protocol form
☑ Data collection instrument(s)
☑ Consent form(s)
☐ *If applicable,* support letter for participant recruitement
☐ *If applicable,* debriefing statement or handouts
☑ Submit **completed IRB protocol with all attachments** to Research & Sponsored Programs (AS 210) or scan packet to ResearchNow@stcloudstate.edu.

CERTIFICATION STATEMENT

KC PI Initial here	**As principal investigator**, I certify that the information provided in this protocol represents a complete and accurate description of the proposed research, this research will not begin until IRB approval received, and this research will be conducted in compliance with IRB recommendations and requirements.
KC PI Initial here	**As principal investigator**, I understand that modifications, significant new findings which develop during the course of the study or increase the risk to participant, or reporting to the IRB any adverse or unexpected events, and that protocols approved as expedited or full require an annual/final report (*protocols approved as exempt do not require continuing review/final report process*). To submit a Continuing Review/Final, please complete the Continuing Review Form
KS Faculty Mentor Initial here	**As faculty advisor**, I certify that I have reviewed this research protocol and that I attest to the scientific merit of this research study. I will advise and provide continued guidance to support the research/study as appropriate for the student's academic development.

Kelli Check Digitally signed by Kelli Check Date: 2018.09.12 19:20:24 -07'00'	September 12, 2018
Signature of Principal Investigator	Date
Kimberly A. Schulze Digitally signed by Kimberly A. Schulze Date: 2018.09.12 11:23:34 -05'00'	September 12, 2018
Signature of Faculty Mentor/Course Instructor	Date

TYPE OF REVIEW REQUESTED

Select **ONE** category that best aligns with your research.

Common Categories for Exempt Review

1) **Research conducted in established or commonly accepted educational settings, involving normal educational practices,** such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2) **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior**, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4) **Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified**, directly or through identifiers linked to the subjects.

STOP: For Exempt Category 4, please complete the Use of Existing Data Protocol

5) **Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine**:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

○ 6) **Taste and food quality** evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Common Categories for Expedited Review

○ 1) **Clinical studies of drugs and medical devices** only when condition (a) or (b) is met.
(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (*Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.*)
(b) Research on medical devices for which (i) an investigational device exemption application (*21 CFR Part 812*) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

○ 2) **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture** as follows:
(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
(b) from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week

○ 3) **Prospective collection of biological specimens** for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

○ 4) **Collection of data through noninvasive procedures** (*not involving general anesthesia or sedation*) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (*Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications*.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

○ 5) **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)**. (*NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)*

◉ 6) **Collection of data from voice, video, digital, or image recordings** made for research purposes.

○ 7) **Research on individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (*NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.*)

8) **Continuing review of research previously approved** by the convened IRB as follows: a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or b. where no subjects have been enrolled and no additional risks have been identified; or c. where the remaining research activities are limited to data analysis.
STOP: For Continuing Review, please complete the Continuing Review/Final Report Form

9) **Continuing review of research, not conducted under an investigational new drug application or investigational device** exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
STOP: For Continuing Review, please complete the Continuing Review/Final Report Form

PROJECT DESCRIPTION

1. Project Summary/Abstract (Limited to 250 words):

Food selectivity and mealtime problems are common in children diagnosed with autism spectrum disorder (ASD). Food selectivity can interrupt appropriate development and lead to disruptive behaviors and familial stress. Escape extinction, a common intervention, can lead to more undesirable behaviors, more health concerns, and fails to teach independent eating skills. This study will aim to treat food selectivity in 3 children diagnosed with ASD by modeling and shaping independent initiations (i.e., tolerating, interacting, tasting, and eating) to food items. A nonconcurrent multiple baseline across participants design will evaluate the effects of the intervention while measuring the participant's affect throughout the mealtimes.

2. Purpose of the research (Limited to 1 sentence):

This study will aim to treat food selectivity in 3 children diagnosed with ASD by modeling and shaping independent initiations (i.e., tolerating, interacting, tasting, and eating) to food items.

3. Research question(s), if applicable include hypothesis:

This study aims to determine if a modeling and shaping approach is successful in increasing food initiations in children diagnosed with ASD.

4. Research design, if applicable, include independent/dependent variables:

A multiple baseline across participants design will be used. The independent variable is the modeling and shaping intervention. The 4 primary dependent variables are tolerating, interacting, tasting, and eating. Tolerating is defined as maintaining or increasing proximity to the plates containing the foods. Interacting is defined as independently manipulating the food with any part of the hand or utensils. Tasting is defined as food passing the plane of the lips or touching the tongue. Eating is defined as consuming a piece or all of the food. The study will also measure the children's affect during the intervention (negative, neutral, or positive).

5. Describe/List in experiential fashion what activities/behaviors participants will be required to complete during the research project:

The participants will sit at a table with a plate of food in front of them. They will be told it's lunch time. They can eat the food on the plate in front of them, but they will never be told they need to. They will be excused after 10 minutes or sooner if they indicate they are done.

6. Description of potential participants:

Number of Participants: 3

Age(s): (●) 0-7 ( ) 8-17 ( ) 18 or above

Describe demographic characteristics of potential participants:

Participants will have been diagnosed with ASD.

7. Potential participants will be ***limited*** to specific populations:

Yes	No	
◉	○	Children (under age 18)
○	○	Prisoners
○	○	Pregnant women
○	○	Economically/educationally disadvantaged
◉	○	Cognitively Impaired; having trouble remembering, learning new things, concentrating, or making decisions that affect everyday life. Cognitive impairment ranges from mild to severe.
○	○	Non-English speaking
○	○	Students of specific/targeted organization where information collected could affect the participants academic standing or reputation if the participant is identified
○	○	Employees of a specific/targeted organization where information collected could affect the participants financial standing, employability, or reputation if the participant is identified
○	○	Other:

If you checked "YES" to any, provide rational for limiting/targeting a specific population and describe safeguards that will be used to protect potential participants:

The purpose of the study is to determine if the intervention increases food initiations in children diagnosed with ASD, as food selectivity is a common occurrence in children with ASD.

8. Techniques that will be used to identify, recruit and access potential participants (check all that apply, and ***at least one MUST be yes*** to explain how potential participants will be recruited):

Yes	N/A	Source	Support Letter Required by IRB
○	◉	Publically available listserves, directories, memberships, etc.	No
○	◉	Non-public listserves, directories, memberships, etc. List Supporting Organization(s):	Support Letter(s) Attached ☐
○	◉	Open advertising via internet/website announcement, bulletin board notices, telephone, letters or other	Advertisement or Script Attached ☐
○	◉	Professor(s) allowing you to distribute materials in their classes; List Professor(s):	Support Letter(s) Attached ☐
○	◉	Independent school(s)/Institutions of higher education willing to provide access to students; List School/College(s):	Support Letter(s) Attached ☐
○	◉	Medical organization(s) willing to provide access to clients/patients: List Agency/Organization(s):	Support Letter(s) Attached ☐
◉	○	Other, please explain:	Support Letter(s) Attached ☐

9. Will participants be compensated for participating in the research? ○ Yes ◉ No
If yes, please provide additional information regarding compensation model:

Compensation Type	Compensation Details
☐ Monetary Amount:	Distribution Model: ☐ Completion of research procedures, OR ☐ Lottery/Give-away
☐ Non-monetary	Describe:
☐ Extra Credits	Describe other extra credit opportunities available to participants:

10. Describe the data to be collected:

Sessions will be video recorded and data will be taken while watching the recordings. Frequency data will be taken on interacting, tasting, and eating behaviors. Partial interval data will be taken on tolerating food and affect.

11. How will data be collected (select all that apply):

Yes	N/A	Data collection Process
○	◉	Surveys or data collection instrument (reminder: submit copy with IRB protocol)
○	◉	Interview guide (reminder: submit copy with IRB protocol)
◉	○	Other, please describe the research procedures and list tasks/activities participants will be asked to complete please explain

All sessions will be video recorded to evaluate whether observers agree on scoring the behaviors of the child and teacher. All videotapes will be stored in a locked file cabinet when not in use, and only those directly involved with the research will have access to the tapes. Following a session, the video will be watched and all data will be recorded using the attached data sheet.

12. How will data collected be anonymous or confidential? (select only one):

○ Anonymous; no names/identifiers will be collected, AND no signed consent form

◉ Confidential; identifiers collected will be not-linked to participant responses (i.e. signed consent is only identifiable data, identifiable data stored in a separate data set for raffles/drawings/give-a-ways, participant follow-up)

For confidential data, explain IN DETAIL the coding process and when the key will be destroyed

Each participant will be given a pseudonym that will be used on all materials and data sheets. All videotapes and data will be stored in a locked file cabinet when not in use, and only those directly involved with the research will have access to the tapes and data. Following completion of the study and any subsequent publication of the results, these videotapes and data will be destroyed after 3 years.

13. How will data be storage and accessed?

Where will data be securely stored (password protected computer, locked file cabinet [include location], encrypted/secure file space, etc.)?

All videotapes and data will be stored in a locked file cabinet when not in use, and will be stored on a password protected hard drive. The file cabinet will be located in a room with a lock.

If applicable, who will have access to the data key?

Only those associated with the study will have access to the data and videos.

Who will have access to the data set?

Me, Justin B. Leaf (my site advisor and Director of Research at Autism Partnership, where the study will be run), and Joseph H. Cihon (Assistant Director of Research at Autism Partnership).

14. How will results data be presented?

Yes	N/A	
◉	○	Data will be presented in aggregate form, with no more than 2 demographics presented together
○	◉	Direct quote will be presented If direct quotes will be presented:

Yes	No	
○	○	Participants will be able to review transcript, and make additions/omissions to quotes
○	○	De-identified quotes will be use; explain de-identification process:

○	◉	Other, please explain

15. The raw data and/or coding key from this research will be destroyed *(Check ONLY one)*:

- ○ when the study is complete
- ○ when my degree is awarded
- ◉ within three years
- ○ other:

RISKS AND BENEFITS

16. What are the anticipated benefits associated with this research?

The main anticipated benefit for the 3 participants is that they initiate with a broader range of foods. These benefits extend to the participants' families as their children might engage in less disruptive behaviors during mealtimes and be open to trying novel foods. Another benefit is that the participants enjoy meal times, as there are no demands placed on them.

17. What are the potential risks associated with this research?

There are no foreseeable risks associated with participation in this study.

18. Does the research involve:

Yes	No	
○	◉	Physical pain, discomfort, or injury from procedures or drugs
○	◉	Undesired and/or unexpected psychological changes *(e.g. depression, anxiety, emotional discomfort, confusion, hallucination, stress, guilt, embarrassment, loss of self-esteem)*
○	◉	Invasion of privacy/absence of informed consent *(e.g. covert observation, review of private medical or educational records, etc.)*
○	◉	Sensitive information *(e.g. alcohol/drug use, sexual orientation, illegal activities, suicidal thoughts, physical/mental illness, violence, depression, gang related activities, psychological/physical abuse, pro-life/pro-choice, relationship issues, etc.)* that could result in social and economic harm *(e.g. civil/criminal liability or damage to financial standing, employability, insurability, reputation, etc.)* if a breach in confidentiality occurred.
○	◉	Deceptive techniques *(e.g. giving false feedback about performance, staging an event or situation, concealing the purpose of the research, etc.)* ***A debriefing statement is required; see the handout on deception and the debriefing process.*** **If yes**, how will subjects be misled *(i.e. what information will be withheld or what false information will be provided)*? Describe when and how this deception will be revealed to subjects and provide a copy of the oral or written debriefing statement.

If you checked "YES" to any, what precautions will be taken to minimize or prevent potential risks, inconveniences, and discomforts (e.g. anonymous data collection, presence of trained personnel who can respond to emergencies, etc.)?

19. The informed consent process begins when you first approach potential subjects and continues throughout your research. Potential participants must understand the nature of the study and the risks and benefits involved if they are to make an informed decision about their participation

Yes	N/A	All projects require consent, which form(s) will be used?
○	◉	Implied Consent; a cover letter/page accompanying a confidential/anonymous survey to adults
○	◉	Informed Consent; a signature form for a study with adult subjects
◉	○	Parental/guardian Consent; a signature form for a study with subjects under the age of 18
○	◉	Child Assent; a signature form for a study with subjects who are between the ages of 8 and 18 If study includes subjects under the age of 18, explain the procedures that will be used to obtain parental/guardian and child/minor assent (when applicable):

20. Develop your consent form, REQUIRED to be submitted with your IRB protocol. **Download the fillable consent template, complete by replacing [text brackets] with details about your study**.