UNIVERSITY OF GEORGIA
CONSENT FORM
Harnessing Communication Preferences to Enhance Its Persistence and Mitigate Relapse of Challenging Behavior

Researcher's Statement
We are asking for your child/ the adult you represent to take part in a research study. Before you decide to let him/her participate in this study, it is important that you understand why the research is being done and what it will involve. This form is designed to give you the information about the study so you can decide whether to be in the study or not. Please take the time to read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called "informed consent." A copy of this form will be given to you.

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This is a multisite study being conducted at the University of Georgia (Joel Ringdahl, PI) and the University of Iowa (Kelly Schieltz, PI; Matthew O'Brien, Investigator). We anticipate 60 participants taking part in this study.

Purpose of the Study
This is a research study. We are inviting the participant or, the adult you represent (henceforth referred to as "the participant") to participate in this research study because the participant has been seen in clinic for concerns related to challenging behavior and has been diagnosed with a developmental disability.

The purpose of this research study is to identify various communication-based treatment strategies that will result in longer maintenance of treatment gains. Specifically, we are interested in how different communication modalities affect treatment when treatment procedures change or new people implement the intervention. We feel this information will help us develop treatments that have longer lasting benefits for individuals who exhibit challenging behavior.

Your child's/The adult you represent's involvement in the study is voluntary, and you may choose for him/her not to participate or to stop at any time without penalty or loss of benefits to which your child's/adult you represent is otherwise entitled. Participation in the study is expected to last about 6 months and consist of weekly clinic visits. Each visit may last 1-3 hours, but typically last an hour.

During the study, we will conduct behavioral assessments to determine under what conditions challenging behavior occurs, identify preferred toys and/or activities, and identify methods of communication. We will also conduct interventions that include providing reinforcers/reward following communication. Finally, we will change the procedures in two ways: (1) we will reduce the rewards received following communication, and (2) we will have the parent/guardian conduct the intervention with full rewards available.

There are no foreseeable major risks of discomforts to the participant. Participants may benefit from this study. This includes identification of the environmental variables related to problem behavior; receipt of communication-based behavioral treatments; and identification of preferred communication strategies, which

have been shown to be helpful to address challenging behavior. You may get this benefit from your healthcare provider if you don't want to participate in this research. The results of their participation may help with implementing interventions for them outside of the clinic. It is hoped that the information gathered across all participants of the study will provide information on improving the treatment outcomes for challenging behavior and teaching communication with individuals with developmental disabilities.

As an alternative to participation, typical clinic visits and process continue to be available. This process is similar to what the individual would experience in the study, but would not necessarily include all aspects of the study (for example, experiencing treatments with different levels of reinforcers/rewards).

If you are interested for your child/adult you represent to participate in the study, please read the additional information on the following pages, and feel free to ask questions at any point.

Study Procedures

If you agree to participate, the participant will be asked to participate in three or four phases of the study. During these phases, a variety of activities will occur (described below). The observations for each phase will take place at our clinic. If you are agreeable, we may conduct some of these observations at the participant's home via zoom.

Phase 1a: Challenging Behavior Assessments

The first phase consists of indirect and direct assessments. First, we will ask you to answer several questionnaires regarding the participant's challenging behavior. Second, we will observe the participant during times when attention is limited, when preferred items are limited, when instructions are delivered, and when leisure items and attention are available. In addition, we might observe while the participant is alone in a room. The situation will change every 5 or 10 minutes. The goal of these assessments is to identify the consequence(s) that are relevant to challenging behavior.

Phase 1b: Communication Assessments

During the first portion of Phase 1b, we will identify the relationship between the relevant consequence(s) for challenging behavior (identified in Phase 1a) and appropriate communicative responses, and/or teach appropriate communicative responses to replace challenging behavior. Specifically, the participant will be provided with rewarding consequences following the use of appropriate communication strategies. During the initial portion of Phase 1b, only one communication modality at a time will result in the consequence. During the second portion of Phase 1b we will identify the participant's relative preference among the various communication modalities. Specifically, the participant will be provided with rewarding consequences following the use of appropriate communication modalities. However, several (i.e., two or more) modalities will be available and exhibiting any of them will result in the consequence.

Phases 2 and 3: Tests of Treatment Maintenance.

Phases 2 and 3 will consist of two tests of treatment maintenance to evaluate how long the participant will continue to use the various appropriate communication strategies when one of two treatment changes is made. Each participant will experience both, but the order in which they are experienced will vary from participant to participant.

One test of treatment maintenance will consist of a reduction in rewards presented following communication. This test will tell us how well the communication strategy holds up to times when communication no longer produces reinforcers from others in the environment.

The other test of treatment maintenance will consist of a novel implementer conducting the intervention. During these sessions, we may ask the parent/guardian to conduct the treatment sessions with coaching from research team staff. Communication will result in delivery of the identified rewards (e.g., access to preferred items) and we will monitor for any return of challenging behavior.

Please provide initials below if you agree to serve as the novel implementer. You may still participate in this study even if you are not willing to serve as the novel implementer.

_____ I do not want to serve as the novel implementer.

_____ I am willing to serve as the novel implementer.

Risks and discomforts
The participant may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

- The participant may become upset or engage in problem behavior when preferred items or attention are removed at the end of a reinforcement interval.
- The participant may engage in problem behavior when instructions are delivered.
- Self-injurious behavior and/or aggression (if the participant has a history of exhibiting these behaviors) resulting in injury to self or others are possible. If behavior causes immediate injury, sessions for the day will be terminated.

The researchers will exercise all reasonable care to protect the participant from harm as a result of his/her participation. In the event that any research-related activities result in an injury, the sole responsibility of the researchers will be to arrange for your transportation to an appropriate health care facility. If you think that you have suffered a research-related injury, you should seek immediate medical attention and then contact Dr. Ringdahl right away at 706-542-4751 or 706-542-9085. Your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

Benefits
There are a few known, short-term benefits to participants. These benefits include identification of the environmental variables related to problem behavior; receipt of communication-based behavioral treatments; and identification of preferred communication strategies, which have been shown to be helpful to address challenging behavior. The long-term benefits related to participation are unknown. However, we are attempting to identify variables that will lead to the development of interventions for challenging behavior that have continued therapeutic impact across time and setting.

We hope that, in the future, other people might benefit from this study because the study may add to our general knowledge regarding the variables that result in the maintenance of treatment success.

Results of your participant's progress in the study will be shared with you.

Alternatives
The participant is under no obligation to participate. You may continue to receive clinical services as deemed necessary by the staff of the UGA Applied Behavior Analysis Support Clinic. The study procedures are similar to what would occur during the course of normal clinical practice.

Incentives for participation
There are no incentives for participation in this study. There are no additional costs for participating in the study.

Audio/Video Recording

One aspect of this study involves making video recordings of the participant. The video recordings will be used to allow a second observer from our research team to observe and score data relevant to the study. These videotapes will be destroyed 10 years from collection.
Please provide initials below if you agree to have sessions video recorded or not. You may still participate in this study even if you are not willing to have the interview recorded. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

_____I do not want to have these sessions recorded.
_____I am willing to have these sessions recorded.

_____I give permission to use these video recordings to train therapists who will work with my child in the future or to train others to perform behavioral work (e.g. in university courses). All therapists or students at UGA will keep any information viewed in the video confidential.
I understand that I can revoke this privilege at any time and my child's services will not be altered.

Privacy/Confidentiality
We will keep the participant's participation in this research study confidential to the extent permitted by law; specifically, researchers will not release identifiable information to anyone other than the individuals or offices identified below without written consent unless required by law. However, it is possible that other people such as those indicated below may become aware of the participant's participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies the participant.

- federal government regulatory agencies,
- auditing departments of the University of Georgia
- The University of Georgia's Institutional Review Boards (a committee that reviews and approves research studies)

In addition, if we witness or observe evidence of abuse experienced by the participant, we are required by law to breach confidentiality and report the event or evidence to the appropriate legal authorities.

To help protect the participant's confidentiality:

- Only information that is pertinent to the proposed study will be collected.
- Confidential information obtained as part of the proposed study will be discussed only with members of the research team and only as needed. All discussion of confidential information will take place in secured locations to which public access is restricted.
- Hard copy records will be stored in locked file cabinets within locked offices and electronic records will be stored on password-protected computers. Only members of the research team will have access to these records, whether hard copy or electronic.
- Electronic filenames will not include the participant's name.
- If we write a report or article about this study or share the study data set with others, we will do so in such a way that the participant cannot be directly identified.

ClinicalTrials.gov
A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify the participant or you. At most, the website will include a summary of the results. ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. You can search this website at any time.

Data Sharing

Data from this study will be submitted to the National Institute of Child and Human Development (NICHD) Data and Specimen Hub (DASH) at the National Institutes of Health (NIH). DASH is a large database where de-identified study data from many NIH studies are stored and managed. Sharing deidentified study data from the participant you represent helps researchers learn new and important things about science more quickly than before.

De-identified study data means that all personal information about the participant you represent (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect the participant you represent personal information to make that code number. The code number cannot be used to identify the participant you represent. The study researchers will never send your personal information to DASH.

It is possible that the participant you represent will participate in more than one study that sends data to the DASH. DASH can connect your participant's data from different studies by matching the code number on your deidentified data from each study. This data matching helps ensure that researchers who use DASH data only count the participant you represent data one time. It also helps researchers who use DASH to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send de-identified study data about the participant you represent health and behavior to DASH. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your de-identified study data must promise to keep the participant you represent data safe and not try to learn your identity. Experts at the NIH who know how to keep your child's/person you represent data safe will review each request carefully to reduce risks to your privacy. Sharing this data does have some risks, although these risks are low; however, this data could be accidentally shared with an unauthorized person who may attempt to learn the participant you represent identity. The study researchers will make every attempt to protect the participant you represent identity.

The participant you represent may not benefit directly from allowing the data to be shared with DASH. The study data provided to DASH may help researchers around the world learn more about brain science and how to help others who have problems with brain science. The NICHD will also report to Congress and on its website about the different studies using DASH data. You will not be contacted directly about the study data your child/person you represent contributed to the DASH. You may decide now or later that you do not want your child's/person you represent study data to be added to DASH. You can still participate in this research study even if you decide that you do not want this data to be added to DASH. If you know now that you do not want your child's/person you represent data in DASH, please tell the study researcher before the end of the communication today. If you decide any time after today that you do not want your child's/person you represent data to be added to DASH, call or email the study staff who conducted this study, and they will tell DASH to stop sharing your study data. Once the participant you represent data is part of DASH, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about DASH, it is available online at http://DASH.nichd.nih.gov.

Certificate of Confidentiality

To help us protect your privacy, we will obtain a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers can refuse to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the FDA.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

However, if we learn about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, we will report that to the proper authorities.

Internet
This research involves the transmission of data over the Internet. Every reasonable effort has been taken to ensure the effective use of available technology; however, confidentiality during online communication cannot be guaranteed

Other Privacy/Confidentiality
We will keep this Informed Consent Document in our research files.
We will retain identifiable information for up to 10 years. The purpose for keeping the information for this length of time is to allow our research team to review the data, disseminate research papers based on the data, and/or prepare applications for externally funded projects based on the data. As described above, steps will be taken to protect identity in any resulting documents.
The information collected in this study may be used/shared after identifiers are removed with other researchers and/or for future studies without additional consent.

Sponsored Research
This project is sponsored by the National Institute of Childhood Health and Human Development (NICHD), part of the National Institutes of Health (NIH).

Conflict of Interest
No conflicts to disclose.

Taking part is voluntary
Taking part in this research study is completely voluntary. You may choose for your child/adult you represent not to take part at all. If you decide for the participant to be in this study, you may stop their participation at any time. If you decide for the participant not to be in this study, or if the participant stops participating at any time, the participant won't be penalized or lose any benefits for which the participant otherwise qualifies. Your decision to participate will not affect current treatment/healthcare services. There are no additional costs to participate in the project.

If you decide for your child/adult you represent to withdraw from the study, the information that can be identified as yours will be kept as part of the study and may continue to be analyzed, unless you make a written request to remove, return, or destroy the information.

It is possible that the researchers may terminate your participation in the study. This might happen if scheduled visits are missed on a frequent basis. In addition, if dangerous behavior is exhibited that cannot be safely blocked or redirected, participation in the study may need to be terminated.

If you have questions

The main researcher conducting this study is Joel Ringdahl, a professor at the University of Georgia. Please ask any questions you have now. If you have questions later, you may contact Joel Ringdahl at ringdahl@uga.edu or at 706-542-9085. If you have any questions or concerns regarding your rights as a research participant in this study, you may contact the Institutional Review Board (IRB) Chairperson at 706-542-3199 or irb@uga.edu.

Research Subject's Consent to Participate in Research:

To voluntarily agree to take part in this study, you must sign on the line below. Your signature below indicates that you have read or had read to you this entire consent form, and have had all of your questions answered.

_____	_____	_____
Name of Researcher	Signature	Date

_____

Name of Participant

_____	_____	_____
Name of Parent/Guardian/Legal Representative	Signature	Date

Please sign both copies, keep one and return one to the researcher.