Cover Page

Official Title: Basic and Clinical Studies in Reinforcing Posi:ve Behaviors in Intellectual and Developmental Disabili:es

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PARENTAL PERMISSION TO PERMIT CHILD TO TAKE PART IN RESEARCH

TITLE OF STUDY: Resurgence as Choice: Basic and Clinical Studies
Principal Investigator: Brian Greer, Ph.D., BCBA-D

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want your child to take part in this study. It is your choice for him/her to take part or not.

The **purpose of the research** is to determine how best to minimize problem behavior during common challenging situations (e.g., when preferred items or attention are unavailable for an extended period). Differential reinforcement of alternative behavior (DRA) procedures are used frequently to decrease problem behavior and increase appropriate behavior. DRA procedures involve withholding the reward given for destructive behavior in the natural environment (e.g., home or school), and providing that reward instead for a communicative request (e.g., exchanging a card, saying "toy, please"). DRA procedures teach children a communication response so that they can get what they want using appropriate means such as asking for things, as opposed to using problem behavior. The goal is to teach children a communication response that replaces problem behavior. For example, if a child engages in aggression to access attention from adults, we use DRA to teach the child to request attention without engaging in aggression. Although DRA is effective, we are investigating ways to enhance these effects. The overall goal of this research is to find the best way to make DRA treatments effective and practical while keeping problem behavior as low as possible. The study will focus on comparing amounts of treatment sessions and methods for making treatments more practical.

Their **time in the study will take** approximately 8 to 16 weeks of their Severe Behavior admission. During Severe Behavior admissions, caregivers 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. Caregiver-run sessions (5- or 10-minute sessions) will be conducted throughout the treatment and will together involve less than an hour of caregiver commitment. The last week of treatment will consist of 8-15 hours of direct caregiver training in clinic and at home to ensure that our results transfer to your home. The amount of time required of you and your child are the standards for typical clinical cases in the clinic.

Possible harms or burdens of taking part in the study may be those similar to routine treatment of problem behavior in that we will expose your child to times in which they cannot get their way. Learning these tolerance skills can be challenging for some children, leading to problem behavior that causes self-harm to the child or harm to the therapists, including bruising. There is also a risk of loss of confidentiality. These risks would be present during typical treatment of problem behavior regardless of study participation.

An alternative to taking part in the research study your child can continue receiving services through the Severe Behavior program at the clinic or through the Douglass Developmental Disabilities Center. Your child's alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of your child if you permit him/her to take part in it. If you have any questions now or during the study, you should feel free to ask them and should expect to be given answers you completely understand. After all of your questions have been answered and you wish your child to take part in the research study, you will be asked to sign this permission form. You are not giving up any of your child's legal rights by permitting him/her to take part in this research or by signing this parental permission form.

Who is conducting this research study?
Dr. Brian Greer is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Greer may be reached at brian.greer@rutgers.edu

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

SPONSOR OF THE STUDY: National Institute of Child Health and Human Development

Why is this study being done?
The purpose of this research study is to determine whether we can reduce the chances of children having problem behavior during treatment challenges by changing the amount of time that the child receives treatment in which they are taught to request what they want in an appropriate manner. We want to know whether increasing the length of DRA treatment will reduce the chance that problem behavior will return when a child is exposed to brief periods of not getting what he or she wants when he or she makes an appropriate request. These brief periods in which children do not get their way after DRA treatment are very common, and the goal of this research is to better understand whether we can prevent problem behavior coming back during these periods by giving the child more experience with DRA treatment.

Who may take part in this study and who may not?
Children receiving services through the Severe Behavior Program at our clinic or at the Douglass Developmental Disabilities Center who are between the ages of 3 and 17, who have stable educational and medical plans and a diagnosis of an intellectual disability, and who engage in severe problem behavior to get their way from adults are appropriate participants for this study. Individuals who are older than 17 or younger than 3, who are currently experiencing changes in medication or educational support, who do not have a diagnosis of an intellectual disability, or who have a diagnosis of a major mental illness or medical problem that would prevent participation, or who engage in severe problem behavior only as a form of self-stimulation, may not be appropriate for this study.

Why has my child been asked to take part in this study?
Your child is being asked to be in this study because they are 3-17 years old, on a stable psychoactive drug regimen and educational plan, and currently receiving services through the Severe Behavior Program at our clinic. Your child is also being asked to be in this study because he or she has been diagnosed with a intellectual disability and engages in severe problem behavior to get adults to respond in a given way (e.g., by providing breaks from work).

How long will the study take and how many subjects will take part?
Your child will complete the study in approximately 8 to 16 weeks of their Severe Behavior admission. We are recruiting 22 children to be in this study.

What will my child be asked to do if s/he takes part in this study?
We will use Differential Reinforcement of Alternative Behavior (DRA) procedures to teach your child an appropriate response to replace problem behavior. During this time, all problem behavior will be ignored so that it no longer results in the desired consequence (e.g., attention, break from tasks, toys), and we will honor each of your child's appropriate requests. For example, if we find that your child's problem behavior is maintained by access to attention, we will stop providing attention when your child has problem behavior, and we will prompt your child to request attention vocally or using a card exchange or card touch. When your child requests without having problem behavior, we will give him or her attention. If we find that your child's problem behavior is maintained by access to a toy, we will stop providing the toy when your child has

problem behavior, and we will prompt your child to request the toy. When your child requests without having problem behavior, we will give him or her the toy. If we find that your child's problem behavior is maintained by getting out of (escaping) instructions or demands, we will continue to present instructions when your child has problem behavior, and we will prompt your child to request a break. When your child requests without having problem behavior, we will give him or her a break.

During the first study, we will compare amounts of treatment sessions (e.g., 4 treatment sessions versus 8 treatment sessions) to determine if few or many treatment sessions are needed to ensure that your child can tolerate challenging situations (e.g., when appropriate requests are denied for a period of time because you are busy on the telephone).

During the second study, we will include cues (e.g., different colored cards; presence or absence of the communication materials) to help your child learn when their requests will be honored or when they need to tolerate requests being denied. Based on your child's performance in previous sessions, we will use mathematical equations to determine how best to increase the amount of time that requests are denied (making treatment more practical for you) while not challenging your child so much that problem behavior returns during the treatment sessions. You may be asked for your child's participant in one or both of the studies.

Some of the sessions will be video recorded. The recordings will be used only for the purposes of data collection and will be kept confidential.

What are the risks of harm or discomforts my child might experience by taking part in this study?
The risks of your child's participation in this research are similar to the risks of usual treatment in our program and no greater than the risks you may currently experience at home working with your child's problem behavior. During the study, we will put your child in situations that may make problem behavior occur more often. However, these treatment procedures are often used in our standard-of-care treatments and are part of the way in which we normally assess and treat behavior problems. Children who often hurt themselves in our program are monitored closely to make sure that the harm they produce is not serious, permanent, or worse than what usually occurs at other times. We will stop what we are doing, block your child from hurting themselves, and consult one of our physicians or nurses if we see any redness, bruising, or bleeding. 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 your 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). If your 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 your child. There is also a risk of loss of confidentiality. The loss of confidentiality is unlikely due to the use of a secured network hard drive to store your child's data.

Are there any benefits to my child if s/he takes part in this study?
This study may decrease your child's problem behavior and teach your child a replacement behavior. Your child may not get any benefit from being in this research study.

What are my alternatives if I do not want to take part in this study?
As an alternative to you and the child participating in this study, you can continue to receive services through the Severe Behavior Program or the Douglass Developmental Disabilities Center.

How will I know if new information is learned that may affect whether I am willing to allow my child to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to allow your child to continue taking part in the study. If new information is learned that may affect your child after the study or their follow-up is completed, you will be contacted.

Will I receive the results of the research?
In most cases, the results of the research can be made available to you when the study is completed and all the results are analyzed by the investigator. The information from this study may be published in scientific journals or presented at scientific meetings, but your child's identity will be kept strictly confidential. If you want the results of the study, contact the Principal Investigator at the email address provided at the beginning of this form.

Will there be any cost for my child to take part in this study?
We will bill you or your insurance company for the research sessions in this study that are considered standard of care. There are no financial costs associated with your child's participation for sessions that are conducted for research purposes only and are not considered standard of care.

Will my child be paid to take part in this study?

Your child will not be paid to take part in this study.

How will information about my child be kept private or confidential?
All efforts will be made to keep your child's personal information in the research record confidential, but total confidentiality cannot be guaranteed. Reasonable steps will be taken to protect you and the child's privacy and the confidentiality of you and the child's study data. That means that your name and the child's name will not be included on any data collection forms and your child's initials will be used instead. Participant information will be maintained for a minimum of six years. Some of the sessions with your child will be video-recorded. Recordings are to be used only for the purposes of data collection and will be kept confidential. Research data will be archived on encrypted servers. The only persons who will have access to the child's research records are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen to my child's information or biospecimens collected for this research after the study is over?

After information that could identify your child has been removed, de-identified data collected for this research may be used by or distributed to investigators for other research without obtaining additional permission from you.

What will happen if my child is injured during this study?
Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include those risks listed in the section above "What are the risks of harm or discomforts my child may experience by taking part in this study?". In addition, it is possible that during the course of this study, new adverse effects of our assessment and treatment procedures that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish my child to take part in the study or if I later decide that I do not wish my child to stay in the study?
It is your choice whether your child takes part in the research. You may choose to have your child take part, not to take part or you may change your mind and withdraw your child from the study at any time.

If you do not want your child to enter the study or decide to stop taking part, their relationship with the study staff will not change, and s/he may do so without penalty and without loss of benefits to which your child is otherwise entitled.

You may also withdraw your permission for the use of data already collected about your child, but you must do this in writing to Dr. Greer at brian.greer@rutgers.edu.

Who can I call if I have questions?
If you have questions about your child taking part in this study or if you feel your child may have suffered a research related injury, you can call:
Brian Greer
Brain Health Institute
683 Hoes Lane West
Office 259A
Piscataway, NJ 08854
(732) 235-6077

If you have questions about your child's rights as a research subject, you can contact the IRB Director at: New Brunswick/Piscataway HealthSci IRB (732) 235-9806 or the Rutgers Human Subjects Protection Program at (973) 972-1149 or email us at humansubjects@ored.rutgers.edu.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOUR CHILD FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your child's medical record in this research. Their information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use

your child's identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my child's information be used?
Your child is being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using his/her health information for this study is to help investigators answer the questions that are being asked in the research.

What information about my child will be used?

- Name
- Date of birth, admission, and discharge
- Medical Record Number
- Full-face photographs and videos

Who may use, share or receive my child's information?
The research team may use or share your child's information collected or created for this study with the following people and institutions:

- Rutgers University Investigators involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your child's information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my child's research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?
No. You do not have to permit use of your child's information. But, if you do not give permission, your child cannot take part in this study. (Saying no does not stop your child from getting medical care or other benefits s/he is eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your child's information (and to stop taking part in the study) at any time. If you take away permission, your child's information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your child's information in the research, you must write to the researcher and tell him or her of your decision: Brian Greer at brian.greer@rutgers.edu.

How long will my permission last?
There is no set date when your permission will end. Your child's health information may be studied for many years.

Consent (Authorization) to Audio-Visually Record or Photograph Subjects

We are also asking for your consent to allow us to take audio-visual video recordings of your child as part of the research. In order for your child to take part in the research, you need to consent to your child be video-

recorded.

The video recordings will be used for purposes of data collection. That is, members of the research team will review the recordings in order to (a) allow a secondary observer to record data on your child's behavior during the study, and (b) allow researchers to ensure that research procedures are implemented with high integrity.

The video recordings may include the following information that can identify your child: your child's name, the date of the video recording, and full-face images of your child. Protected health information not required for the purposes of the video recording will be omitted (e.g., child birth date, medical record number).

The video recordings will be stored on an encrypted server and on encrypted laptop computers. The electronic file folders in which the video recordings will be stored will be labeled with your child's name while the study is being conducted with your child. After your child has completed the study, these file folders will be labeled with a unique code number linked to your child. Study personnel will retain video recordings for up to six years. The only persons who will have access to these recordings are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law.

The video recordings will not be used by us or distributed to investigators for other research.

Your signature on this form permits the investigator named above to record your child as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than those stated in the consent form without your written consent.

PARENTAL PERMISSION FOR CHILD

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

I am the [ ] parent or [ ] legal guardian of _____(name of child) and I agree for my child to take part in this research study.

Subject/Child's Name (Print):_____

Parent or Legal Guardian Name (Print):_____

Parent or Legal Guardian Signature:_____Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent Name (Print):_____

Signature:_____Date: _____