

**Principal Investigator: Judy Reaven, Ph.D.**

**Consent form for: PARENTS**

**COMIRB No: 18-0114**

**Version Date: v06.13.19**

**Study Title: Facing Your Fears in Schools: Implementing a CBT Program for Students with ASD or Other Special Learning Needs**

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You and your child are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

**Why is this study being done?**

The purpose of the study is to treat symptoms of anxiety in children with autism spectrum disorder (ASD) or social communication difficulties within a school setting. Symptoms of anxiety are very common in children with ASD or social communication difficulties. This research project uses a cognitive behavior therapy (CBT) approach to treat these symptoms. This CBT program is called Facing Your Fears: A School Based Program (FYF School Program). CBT has been shown to be useful in reducing anxiety in children with ASD or social communication difficulties. Although the CBT approach used here is considered standard of care, the delivery of CBT in schools is novel. We would like to learn whether CBT approaches delivered in school settings will help your child experience less anxiety and participate more fully in school activities.

You are being asked to be in this study because you are a parent of a child who meets these criteria: (1) Has symptoms of anxiety (2) is between 7 and 15 years old (3) Has a verbal IQ of 70 or greater, and (4) currently has an IEP or 504 plan.

Up to 150 school providers will be included; additionally, up to 50 school based trainers, and 200 teacher informants will also be included. We plan to include up to 200 students with ASD or social communication difficulties from the Denver/metro area, along with up to 200 parents.

**What happens if I join this study?**

There are five steps to the study. If you and your child agree to join this study you will be asked to do the following:

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## **Consent and Authorization Form**

**Step 1: Learn about Study and Sign Forms:** The first step is to meet with the research team to learn about the study. If you choose to take part, you will then sign the consent forms. You will also be asked to sign a form that will allow the researchers to gather school records for your child. You will also be asked to sign below to allow us to videotape your child's participation in group intervention sessions.

**Step 2: Child Testing and Adult Completion of Questionnaires:** The second step involves completing questionnaires online or on paper regarding your child's history including medications, anxiety, behavior, and other mental health concerns related to your child. Completing these forms will take 30-60 minutes.

Your child's teacher will also be asked to complete questionnaires about your child's social interactions, anxiety, and behavior in a school setting. This will happen after he/she is consented for participation in this study.

Your child may be asked to complete additional testing at school to assess their developmental level and social skills. These assessments will take place at their school and take approximately 1 hour.

The information from these forms and from these testing sessions will be used to decide if your child is eligible for this study. If your child is found not to be eligible for the study, then we will tell you this directly following the testing.

**Step 3: Selection of Other Group Members:** In addition to your child, school personnel will select up to 3 other children to participate in the study. These students and their parents will also take part in a consent process.

**Step 4: Participate in Facing Your Fears: A School Based Program:** Your child and the consented students will be randomized to take part in the FYF – SB Program either in the Fall or Spring semesters. The FYF - SB Program will consist of a child component and a parent component. Sessions for your child will be conducted weekly for up to 60 minutes and continue for a semester. School providers will likely schedule the sessions for during the school day. Every effort will be made to minimize the amount of time that your child misses academic work. If you, your school team, and other parents agree, the sessions with your child may occur after school. You will be asked to attend up to 3 group sessions that will run for 60-90 minutes. All sessions will be videotaped. You and your child will rate the treatment.

**Step 5: Follow-up Assessment:** At the end of each school semester, you, your child, and your child's teacher will complete several questionnaires related to your child's anxiety, behavior, and other mental health concerns. You and your child will spend approximately 30-60 minutes completing these questionnaires.

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Your involvement will last for the school year.

### Recorded Information

In this study we will be recording evaluations, assessments, and therapy groups. We will use computer files and DVD/CD's. We will keep this information secure and private. We will store it for 7 years. At the end of that time, we will destroy it.

The use of any recordings will be for the following purposes (*initial all approved uses*):

1. Future research. \_\_\_\_\_
2. Training of research personnel. \_\_\_\_\_
3. Training of pre-professional students. \_\_\_\_\_
4. Training of professionals. \_\_\_\_\_
5. Public awareness. \_\_\_\_\_

All video recordings will be kept under lock and key. All recordings will be protected and used only for the purposes for which you have given permission as indicated above.

The use of any recordings will be done in a legitimate manner which is not intended to cause embarrassment or harm, and your confidentiality will be maintained.

All recordings will be held and used for only the above purposes. The recordings may be kept indefinitely, or for an unknown amount of time.

### Being placed on a recruitment list for future studies

We may be doing other studies in the future, and would like to make a list of people who are interested in doing more studies. If you decide now that we can keep your name on a list, you can change your mind anytime. If you change your mind, contact Dr. Judy Reaven and she will remove your name from the list.

I would like to be included on a list of people who will be contacted about future studies.  
\_\_\_\_\_ Initials

I would not like to be included on a list of people who will be contacted about future studies. \_\_\_\_\_ Initials

### Anxiety Disorders Interview Schedule (ADIS)

The Anxiety Disorders Interview Schedule (ADIS) is a structured measure designed to help identify problem behaviors in children with anxiety. These problems may include school refusal behavior, separation anxiety, social phobia, specific phobia, panic

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disorder, OCD, and PTSD. We would like to use this measure to interview you at a time and place of your choosing in order to better understand your child and his/her needs.

The data collected during this interview will be used only for research purposes within this study. It will not be included in your child's medical or school record.

This interview will take about 2 hours to complete. You will receive additional reimbursement if you choose to complete this interview.

I would like to be interviewed using the Anxiety Disorders Interview Schedule (ADIS).

\_\_\_\_\_ Initials

I would not like to be interviewed using the Anxiety Disorders Interview Schedule (ADIS). \_\_\_\_\_ Initials

### **What are the possible discomforts or risks?**

Your child may experience some discomforts in this study. Possible discomforts include the possibility of increased anxiety when engaged in the FYF - SB Program. This might be because the group will be focused on talking about anxiety which could result in discomfort.

In addition, your child will be facing fears a little at a time which could also cause discomfort. Your child may miss academic opportunities. However, every effort will be made in discussions with the school providers for children not to miss academics and work will be missed only with your permission.

Other possible risks include loss of confidentiality. Every effort will be taken to maintain confidentiality of all treatment data and all school context and process information.

The study may include risks that are unknown at this time.

### **What are the possible benefits of the study?**

This study is designed to reduce anxiety. While there is no guarantee that your child's anxiety will improve, it is hoped that your child's anxiety will be reduced following involvement in this study.

### **Are there alternative treatments?**

There may be other school-based treatments for your child's anxiety. These treatments include other methods of increasing coping skills. You may also choose to get no treatment. You should talk about other treatments with your child's school team. Make

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sure that you understand all of your choices before you decide to take part in the study. You may also withdraw from the study and still have these other treatments available to you.

### **Who is paying for this study?**

The study is funded through a grant from the Health Resources and Services Administration (HRSA) to Dr. Reaven.

### **Will I be paid for being in the study? Will I have to pay for anything?**

You will be given a gift card for completion of pre and post treatment assessments. There will be an additional gift card for those that choose to complete the optional ADIS interview. There are no costs to you for being in the study.

There will be no charges for any procedures required by the study.

### **Is my participation voluntary?**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. Whether or not you choose to participate will have no effect on any treatment or any other services that you or your child receives within your school. The only school services that will change are the additional supports that are part of this study. You might be able to get additional mental health supports for your child outside of the study. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Dr. Reaven may decide to stop your participation without your permission if she thinks that being in the study may cause your child harm, or for any other reason.

### **Who do I call if I have questions?**

The researcher conducting this study is Dr. Judy Reaven. You may ask any questions you have now. If you have questions later, you may call Dr. Judy Reaven at (303) 724-7646. You will be given a copy of this form to keep.

You may have questions about your rights as a participant in this study. You may call the Colorado Multiple Institutional Review Board (COMIRB) office at (303) 724-1055.

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### Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver
- Littleton Public Schools
- Denver Public Schools
- Cherry Creek School District
- Joshua School

We cannot do this study without your permission to see, use, and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

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Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

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- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- The Health Resources and Services Administration (HRSA) who is the agency paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

### **Information about you that will be seen, collected, used and disclosed in this study:**

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Research Visit and Research Test records

### **What happens to data that are collected in this study?**

The data and information collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use, or sale of such a product or idea.

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### HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

\_\_\_\_\_ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

\_\_\_\_\_ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

### Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study. I will get a signed and dated copy of this consent form.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Consent form explained by: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

\_\_\_\_\_  
Legally Authorized Representative/  
Proxy Decision Maker

Date \_\_\_\_\_

Print Name: \_\_\_\_\_

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