

**INFORMED CONSENT FORM
PARENT/LEGAL GUARDIANS**

Sponsor / Study Title: The Organization for Psychoeducational Tutoring / “Observational Research Related to Psychoeducational Tutoring”

Protocol Number: JS01

**Principal Investigator:
(Study Director)** Joseph M. Strayhorn, Jr., M.D.

Telephone: 607-319-0880

Address: Office of Joseph Strayhorn, M.D.
205 Willard Way
Ithaca, NY 14850

We are asking you and your child to participate in a research study. This form is designed to give you information about this study. We will describe this study to you and answer any of your questions.

What the study is about

This research is for families served by the Organization for Psychoeducational Tutoring (OPT). OPT delivers teaching designed to improve psychological and/or academic functioning. Such teaching may include training for parents and tutoring delivered directly to the child. This teaching is called psychoeducation. The teaching is conducted in phone sessions.

The research aims to see how much good the teaching accomplishes. It also aims to help decide how best to measure psychological functioning. To evaluate our program, we wish to gather information on how each student is doing, every six months, for at least 2 years, and, if possible, 3 years. The information gathered will also be used for statistical analysis and scientific study. The results may appear in scientific journals.

We hope to include data from about 100 additional participants.

What we will ask you to do

We ask that you, the child’s parent or legal guardian, be available for phone interviews for about two hours every six months, and also to fill out some questionnaires every six months. At these assessment occasions, we will also interview your child and do some testing of verbal ability, reading ability, or psychological skills, by telephone. We may also ask for a questionnaire to be filled out by your child’s teacher, and/or for you to supply to us or allow the school to supply to us your child’s report card data and testing data. All the information will be recorded

so that it can be analyzed statistically and results reported, in ways that do not permit identification of any individual. Some of the reporting of results will be through analysis of group data; some of it may take the form of case reports, telling the story of results with an individual. In case reports, caution will be taken to omit or alter any information that would enable anyone to figure out whom the report was written about. We will give you the opportunity to review and or make any changes to any individual case report we have about your child.

In psychoeducational tutoring, the child will receive half hour phone sessions with a tutor who teaches academic and/or psychological skills, 3 to 6 times a week for at least a year. Parent training may accompany the tutoring. The tutoring is provided at no cost to you.

Risks and discomforts

The questionnaires used in this study may make you or your child feel uncomfortable. You and/or your child do not need to answer any questions that you or your child are not comfortable with.

For the data gathering, you have to spend some time.

For any type of education, if your family participates in it, there are risks of harm which we consider minimal. A tutor or trainer may say something inappropriate or do a bad job in some other way. Or your child may develop an attachment to a tutor and feel bad when the tutor has to finish his or her employment. The time spent in tutoring may displace other activities. The curricula we use may include at least one thing you disagree with. We estimate the risks of the psychoeducational interventions to be less than those of attending an ordinary school.

During the course of your participation, if we become aware of any new and significant findings that may affect your willingness to continue, we will disclose these to you.

Benefits

F We hope and expect that the training we provide is useful. The benefits may include lasting improvement in psychological skills, academic skills, and life satisfaction for the child, and a better emotional climate for the family. Benefits are not guaranteed. Part of the purpose of this research is to keep track of the effects of this method of delivering services in order to find out more about what it can achieve.

Alternatives

There are many ways to measure or improve a child's academic and psychological skills. You are free to engage any other methods of helping your child that you wish -- clinical, educational, or others -- instead of OPT, or in addition to it, at any time you wish.

Lack of Payment

You do not have to pay for these services, and you will not get paid anything for participating in the research.

Privacy/Confidentiality

Any information with identifiers, for example people's names, attached to it will be kept under lock and key if on paper, and in encrypted, password-protected locations if in electronic form. A separate communication has to do with privacy and confidentiality considerations and the HIPAA privacy act.

Confidential information which identify you by name will be accessed by the study director, and the sponsor or persons working on behalf of the sponsor and under certain circumstances, the Institutional Review Board that oversees the ethics of the study, or by regulatory authorities (such as the United States Food and Drug Administration (FDA)) if required by law in order to check that the study is conducted properly.

Please note that email communication is neither private nor secure. Though we are taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party. This means that absolute confidentiality cannot be guaranteed.

Taking part is voluntary

Your involvement in the research is voluntary. You may refuse to participate from the beginning or discontinue at any time for any reason without penalty or loss of benefits to which you are otherwise entitled. Once withdrawal of consent is communicated to the study director, no additional information will be added to the research data set. However, please note that any information collected up to the point of your withdrawal cannot be removed from the study. If psychoeducation is being delivered, this will cease upon withdrawal of consent.

Please do not consent to this study if you are not willing to be contacted every six months for 3 years for follow-up information on your child, and to take the time to furnish information about your child's functioning.

Whom to contact about this study

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044
- or call **toll free:** 877-992-4724
- or by **email:** adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00022063.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information, and have received answers to any questions I asked. I consent for my child and my family to take part in the study. I certify that I am the child's parent or legal guardian, and I am authorized to give consent.

Child's Name (printed) _____

Your Name (printed) _____

Your Signature _____ Date _____

Your relationship to the child: _____

Signature of person obtaining consent _____ Date _____

Printed name of person obtaining consent _____