

# *TherapyWorks L.L.C.*



P.O. Box 854, 19 Halls Road, Suite 204

Old Lyme, CT 06371

Phone: (860) 434-5524

Fax: (860) 434-3262

[www.TherapyWorksCT.com](http://www.TherapyWorksCT.com)

## BERARD AUDITORY INTEGRATION TRAINING INFORMED CONSENT FORM

**Participation:** Participation in auditory integration training is voluntary. You have the right to not participate or to stop participation at any time. Your participation is with the understanding that the auditory integration training device (Audiokintron) is classified as a medical device by the FDA and research on auditory integration training is ongoing. The Earducator is considered an educational training device and as such, is not under FDA jurisdiction.

**Listening Sessions:** The auditory integration training sessions will consist of 10 hours of listening, provided in 30-minute sessions over a period of 10 days. There will be a three to four hour time period between the first and second sessions of each day. The training “music” will be played through headphones at a relatively high decibel level (i.e. loud), but within OSHA guidelines and below the individual’s threshold of discomfort.

**Data Collection:** Data collection allows us to monitor progress following AIT. Participants will be expected to complete sets of questionnaires prior to their training, during training and the completion of the training. Questionnaires will also be mailed to you periodically to be completed and immediately returned in order to monitor progress for a follow up period.

The data collected will be used by TherapyWorks LLC for its own studies, and will be used in collaboration with other researchers in the fields of auditory training, autism, communication disorders and learning disabilities. The results from the research may be presented at parent groups, college classes, professional conferences and seminars, and published in scientific journals. The participant’s identity will remain anonymous when reporting these findings.

**Assessment of Potential Benefits:** Some of the benefits may include a decrease in hypersensitivity to sounds, an increase in auditory comprehension, improved attention and an increase in social behavior. We cannot assure any benefits to the participant at the present time. It is hoped that further research will help determine what type of individuals will benefit, in what ways they will benefit, and who may not benefit from the training.

Dr. Berard, who developed the auditory integration training method used by this office, asserts that people who have auditory peaks in their hearing based on the audio test, will likely benefit from the training. It is also possible that individuals may benefit if their audio tests do not show peaks or if reliable audio tests are unavailable from individuals unable to participate in audio testing.

**Assessment of Potential Risks:** It is possible that for some participants may exhibit physical and/or behavior problems for a period of time during or following the auditory training. This may include problems such as fatigue, occasionally headaches, and brief periods of insomnia. Behavior problems may include tantrums, aggression towards others, or self-aggression, hyperactivity and irritability. Problems other than those listed also may occur.

Dr. Berard believes that these reactions may indicate that the auditory integration training is being effective and producing a change in the participant. Therefore, one should not be alarmed if reactions occur. At the

same time, Dr. Berard's experience has shown the training to be effective even if the participant has no reactions.

Some of these reactions were evident in the control group of the initial pilot study in Oregon, even though they did not receive the auditory integration training. It is possible that some of these reactions are due to the stresses of travel and changes of schedule and environment involved during the training sessions. Further research should provide more information in the area.

I understand that if my son/daughter should experience physical and/or behavior problems at any time during or after the auditory integration training sessions, I will not hold responsible Megan Grills, TherapyWorks LLC, nor any of the office's staff or any other person associated with the training, for the physical and/or behavior problems as well as any injury to him/herself, any injury to another person (including myself), and/or any form of emotional distress experienced by my son/daughter and/or by another person.

Informed Consent: If you agree to have your child participate in auditory integration training, please sign and return both pages of the consent form. A signed consent form means that you have read and understand the potential risks and benefits, and that you have agreed to have your child participate in auditory integration training, and you have agreed to allow TherapyWorks LLC to use data collected from your child's participation in the training as outlined above. The consent form will be reviewed with you on your initial visit to the office.

\_\_\_ Yes. I give my consent to have \_\_\_\_\_  
(name of participant)

participate in the auditory integration training. I have read, understand and agree with the information presented in the consent form.

Signature of Participant \_\_\_\_\_ Date \_\_\_\_\_ (if applicable)

Signature of Parent/Guardian \_\_\_\_\_ Date \_\_\_\_\_

Printed Name of Parent/Guardian \_\_\_\_\_