



To Individuals with Autism Spectrum Disorders and/or their Guardians,

Re: Invitation to participate in a research study on: **Digestive Enzyme Treatment Study for Children and Adults with Autism**

We are inviting participation in a 2-month treatment study to evaluate the effect of a digestive enzyme. This study has been approved by the Human Subjects Institutional Review Board at Arizona State University.

There will be an optional 1-hour initial presentation in Irvine, CA (16251 Laguna Canyon Road, Suite 175), to explain the study. The rest of the study will be done by phone, mail, and email contact with Monica Goings, a graduate student at Arizona State University, working under the supervision of Prof. Adams and Dr. Lin. There is no other need to travel for this study.

The treatment study will involve the consumption of a digestive enzyme with each meal and major snack every day for two months.

Individuals with autism (or their parents/guardians) will be asked to fill out forms at the beginning and end of the study to evaluate the symptoms of autism (about 20 minutes) and gastrointestinal symptoms (3 minutes).

1/3 of the participants will receive Digestive Enzyme 1 (for carbohydrates and sugars) and 1/3 will receive Digestive Enzyme 2 (for carbohydrates, sugars, fats, and protein), and 1/3 will receive a placebo. The enzyme is to be taken with each meal and large snack of each day of the two-month treatment. This study will not involve any medical testing.

Each participant will be contacted on weeks 1, 4, and 8 by phone or email, to check on the participant's health, check on any changes in symptoms, and answer any questions about the study.

Eligibility Criteria:

- 1) Diagnosis of autism spectrum disorder (autism, PDD-NOS, or Asperger's) by a psychiatrist, psychologist, or developmental pediatrician
- 2) Verification of diagnosis by SRS questionnaire
- 3) Age of 2.5 years to 60 years
- 4) No major changes in behavioral or medical treatments in the previous two months, and no intention to make such changes during the 2 months of the study.
- 5) No usage of digestive enzymes in the previous three months.

If you/your child meets the above criteria, we are inviting your voluntary participation in our study. **If you choose not to participate or to withdraw from the study at any time, there will be no penalty.** The results of the research study may be published, but your name will not be used, and we will maintain confidentiality of your test results.

Cost/Payments:

There is no cost to participate in this study.

Possible Side-Effects/Safety Issues:

Digestive enzymes can cause irritation if left in the mouth for a long time (15 minutes), but this risk is eliminated by swallowing them as pills or mixing them with juice.

Thank you for your interest in the study, which will help evaluate the effect of a digestive enzyme for children and adults with autism spectrum disorders.

If you have any questions concerning the research study, please call the study staff Monica Goings at (602) 349 5902 or email mgoings@asu.edu. Thank you very much for your time.

Sincerely,

James B. Adams, Ph.D.
President's Professor, Fulton Schools of Engineering
Graduate faculty in Chemistry and Biochemistry
Director, ASU Autism/Asperger's Research Program
Arizona State University

Thomas Lin, MD
Pediatrician
Irvine, CA

**Application Form for Participation in
Digestive Enzyme Treatment Study for Children/Adults with Autism**

Name of Participant _____
Parent/Guardian's name (if applicable) _____
Mailing Address: _____
City: _____ State _____ Zip _____

Phone: _____ Email: _____
Participant's birth date _____ Gender: _____
Participant's Ethnicity: Asian/Pacific Islander American Indian/Alaskan Native
Black (not Hispanic) Hispanic Multi-Racial White (not Hispanic) Other

Medical Information

Participant's primary diagnosis
(autism, Asperger's, PDD/NOS, or typical/control) _____

Person who made diagnosis and their profession: _____

Other co-existing physical or mental health conditions: _____

Current Medications (including allergy medications):

Current Nutritional Supplements:

Digestive Enzymes:

Special Diet: (please describe):

Is your child currently on chelation therapy? If yes, please describe.

Is your child currently receiving habilitation services or behavioral therapy, such as Applied Behavior Analysis (ABA) or similar therapy? Yes No

If yes, please answer the following:

Average number of hours/week _____

Do you think that, on average, your therapists are:

Untrained; slightly trained; somewhat trained; well-trained; expert

Is your program supervised by a behavior consultant? _____

If yes, how many hours/month do you meet with them? ____ hours/month

Is your consultant a Board Certified Behavior Analyst or Board Certified Associate Behavior Analyst? _____

Overall, how would you rate the effectiveness of your habilitation/behavioral program on your child's learning:

Minimal; modest; moderate; significant; highly effective

Other comments about your program (optional):

Please return this form to:

**James B. Adams
Arizona State University
PO Box 876106
Tempe, AZ 85287-6106
(480) 727-9321 (fax)**