

Memorandum
Narongsak "Dr. Ab" Boonswang, MD
ClinicalTrialsIHR@protonmail.com

17 September 2019

Re: Amaranth Life Sciences ASD Clinical Trial Participation

To Parents and Participants:

This letter is provided to introduce our Autism Spectrum Disorder (ASD) clinical trials for a special formulation medical food provided by Amaranth Life Sciences Pharmaceutical, Inc. to parents and participants in the clinical trials. I am the Principal Investigator (PI) on the trials which are being conducting in cooperation with the Institute for Health Research. I am a physician licensed in the State of Florida.

It has been my clinical experience, and that of other physicians, that the Amaranth formulation as a medical food shows very significant potential for the dietary management of ASD under the Orphan Drug Act of 2005, based on general scientific principles. The proposal is to conduct clinical trials, with up to a thousand participants in a double blind, placebo controlled protocol for up to one year. The clinical trial will feature caregiver reporting.

Participants in the trials will need to complete certain documentation in order to qualify. Please go to this link to read the Clinical Trial Documents, including the Institutional Review Board approved Protocol: <http://www.inhere.org/autism-spectrum-disorder-clinical-trial/>

Please complete the attached:

- [1] Participant Information Form [all information confidential]
- [2] Informed Consent Form
- [3] Medical History Form [all information confidential]
- [4] ASD Symptoms Self-Reporting Form [all information confidential]

Please email the completed forms to this email address: ClinicalTrialsIHR@protonmail.com

This Clinical Trial is being funded through participant payments (\$200 to cover discounted first month costs – an \$800 value) and, going forward, by Crowd Funding by the Institute for health Research. You may contribute to the Trial with any debit or credit card here: [PayPal.me](https://www.paypal.com) or through our Chesed Fund crowd funding page, <https://tinyurl.com/AutismMedicalManna>

We have posted a short video about our Trial here: <https://www.youtube.com/watch?v=N1YVWIwM-nE>

I look forward to working with you on this important Clinical Trial.

Sincerely,
Ab Boonswang
Ab Boonswang MD

AUTISM SPECTRUM DISORDER CLINICAL TRIAL

AMARANTH LIFE SCIENCES PHARMACEUTICAL, INC
AUTISM SPECTRUM DISORDER (ASD) CLINICAL TRIAL
PARTICIPANT INFORMATION FORM
Dr. Narongsak "Dr. Ab" Boonswang
Principal Investigator

The information inserted into this form is private and confidential and may only be used with identity masked, for the purposes of the Clinical Trial, under IRB oversight.

Participant _____

Date of Birth _____

Age at Diagnosis _____

ASD Diagnosis _____

Parent or Guardian _____

Address _____

Phone/Cell _____

Email _____

Comments _____

Included herewith as part of the private and confidential records of the Clinical Trial:

- [1] Informed Consent Form
- [2] ASD Symptom Self-Reporting Forms
- [3] Clinical Trial Medical History Form

Reviewed by:
Date:

**REQUEST, PRIVATE LICENSE,
INFORMED CONSENT AND RELEASE**

Participant:
Address:

Date:
Phone:

For good and valuable consideration, the undersigned agree and certify:

Informed Consent and Release

1. The undersigned understands that the Principal Investigator (PI) and any organization through which the PI conducts research evaluations is for, charitable, scientific research and educational purposes. **The organization and PI do not diagnose, prescribe for, or treat disease conditions; nor do they claim to prevent, mitigate or cure disease conditions. All participants are assumed to have been correctly diagnosed with Autism Spectrum Disorder (ASD).**

The AMARANTH ASD MEDICAL FOOD CLINICAL TRIAL IS FOR RESEARCH PURPOSES ONLY.

2. The undersigned does hereby give ***Informed Consent*** for the dietary supplement medical food research to be conducted by the PI and others. The organization and PI make no medical claims, nor assume any responsibility for any claims. **In no way do they claim that the nutritional product should or can be used to treat any disease condition. The undersigned has studied the alternatives and personally chose the work that is to be done.**

3. **The organization and PI do not make any representations, promises or guarantees. The recommendations and modalities used are not intended to, and will not, prevent, mitigate, treat or cure any disease condition, including, but not limited to, ASD.** The clinical study is a self-reporting, through regular caregiver reports, of potential benefits as a medical food for the dietary management of a medical condition based on medical evaluation and general scientific principles.

4. The undersigned does hereby accept full responsibility for the use of the product and any placebo, ***releasing, indemnifying and holding the organization and PI harmless*** from all claims arising from participation in these procedures. The undersigned acknowledges that the PI does not diagnose, treat or claim to prevent, mitigate or cure human disease.

5. **The undersigned does hereby give the organization and Practitioners permission to use the information gathered during these procedures, with personal identification removed (anonymous data), for research and educational purposes.**

Dated: _____, 200____.

Signature of Participant or Authorized Caregiver:

Name:

Witness:

Name:

AUTISM SPECTRUM DISORDER CLINICAL TRIAL

ASD Caregiver Checklist for ASD Medical Food Clinical Trial – Prior to Clinical Trial

Caregiver to Evaluate Each Symptom/Factor on a 1 to 5 scale*:

- 1 – Not a significant factor, or no improvement in symptom
- 2 – Very Minor factor, or very slight improvement in symptom
- 3 – Minor factor, or slight improvement in symptom
- 4 – Significant factor, or significant improvement in symptom
- 5 – Very significant factor, or very significant improvement in symptom

I. Social communication / interaction behaviors may include:

1. Making little or inconsistent eye contact
2. Tending not to look at or listen to people
3. Rarely sharing enjoyment of objects or activities by pointing or showing things to others
4. Failing to, or being slow to, respond to someone calling their name or to other verbal attempts to gain attention
5. Having difficulties with the back and forth of conversation
6. Often talking at length about a favorite subject without noticing that others are not interested or without giving others a chance to respond
7. Having facial expressions, movements, and gestures that do not match what is being said
8. Having an unusual tone of voice that may sound sing-song or flat and robot-like
9. Having trouble understanding another person's point of view or being unable to predict or understand other people's actions

II. Restrictive / repetitive behaviors may include:

1. Repeating certain behaviors or having unusual behaviors. For example, repeating words or phrases, a behavior called *echolalia*
2. Having a lasting intense interest in certain topics, such as numbers, details, or facts
3. Having overly focused interests, such as with moving objects or parts of objects
4. Getting upset by slight changes in a routine
5. Being more or less sensitive than other people to sensory input, such as light, noise, clothing, or temperature

III. People with ASD may also experience sleep problems and irritability. Although people with ASD experience many challenges, they may also have many strengths, including:

1. Being able to learn things in detail and remember information for long periods of time
2. Being strong visual and auditory learners
3. Excelling in math, science, music, or art

IV. Risk Factors – Use a Y or N for Yes or No instead of the 1 to 5 scale.

1. Having a sibling with ASD
2. Having older parents
3. Having certain genetic conditions—people with conditions such as Down syndrome, fragile X syndrome, and Rett syndrome are more likely than others to have ASD
4. Very low birth weight
5. Vaccine adverse reaction
6. Other drug adverse reaction
7. Gastro-intestinal disorders

* Symptoms primarily from: <https://www.nimh.nih.gov/health/topics/autism-spectrum-disorders-asd/index.shtml>

PARTICIPANT MEDICAL HISTORY

NAME _____ DATE: ____/____/____

Please print clearly

GUARDIAN: _____

ADDRESS: _____

TOWN: _____ STATE: _____ ZIP: _____

HOME PHONE: (____) - ____ - ____ BUSINESS PHONE: (____) - ____ - ____ CELL (____) - ____ - ____

FAX: (____) - ____ - ____ E-MAIL _____

OCCUPATION: _____ POSITION: _____

MEDICAL DOCTOR: _____

CHIROPRATOR: _____

NUTRITIONIST: _____

CHURCH: _____

BLOOD TYPE: _____ BASAL BODY TEMPERATURE _____

Underarm temperature laying in bed
1st thing in the morning.

HEIGHT: ____ WEIGHT: ____ WAIST ____ HIPS ____ [Continue on Reverse for Information Below.]

MAIN COMPLAINT: _____

LIST EACH DIAGNOSIS AND YEAR GIVEN: _____

LIST PREVIOUS MEDICAL INTERVENTIONS (Including vaccinations , radiation, surgery and “chemo.”

Please acknowledge by checking each box below that you understand:

(1) I am voluntarily participating in this Clinical Trial by agreeing to the Clinical Trial Informed Consent form.

(2) This Clinical Trial is organized under a written Protocol approved by an Independent Review Board, available at www.InHeRe.org.

AUTISM SPECTRUM DISORDER CLINICAL TRIAL

[] (3) No promises have been made that the Medical Food will treat Autism Spectrum Disorder (ASD) or its symptoms.

[] (4) To continue to participate in this Clinical Trial designated caregiver will submit, with this Medical History and at least monthly thereafter a completed copy of the ASD Symptoms Self-Reporting Form (below as page 3)

[] (5) Participant or guardian agrees to pay the first month costs of \$200.

Please place a check in the area next to "YES" or "NO" at the end of each of the following:

Do you drink coffee Yes ___ No ___

Do you smoke? Yes ___ No ___

Do you drink coke/diet coke or soda? . . . Yes ___ No ___

Do you consume wine, beer, or alcohol? Yes ___ No ___

Colds, Flues, per year # _____ Yes ___ No ___

Do you sleep soundly? Yes ___ No ___

Sleep per night _____ hours

Have you done enemas? Yes ___ No ___

Have you had colonics? Yes ___ No ___

Have you had spinal adjustments? Yes ___ No ___

Have you fasted in the last year? Yes ___ No ___

Do you have a vegetable juicer? Yes ___ No ___

Do you own a blender? Yes ___ No ___

Do you have a gym membership? Yes ___ No ___

Do you exercise? Yes ___ No ___

Types: _____

How often/Hours per week: _____

How long? _____

Desire to improve eyesight? Yes ___ No ___

Desire to strengthen spine? Yes ___ No ___

Desire to strengthen heart? Yes ___ No ___

Desire to strengthen muscles? Yes ___ No ___

Do you have a rebounder? Yes ___ No ___

Are you able to swallow pills? Yes ___ No ___

Satisfied with your current weight? Yes ___ No ___

Have you been on a supervised Nutrition

program previously?..Yes ___ No ___

Dates: _____

List medications for: _____

Other Information Health Care Providers should know about you:

Have you been bed ridden in the past
2 years. Yes ___ No ___

Chemotherapy in last 3 years Yes ___ No ___
of treatments _____

Dates: _____

Radiation in last 3 years Yes ___ No ___
of treatments _____

Dates _____

Major surgery in last 3 years . . Yes ___ No ___
List Type/Date _____

List Type/Date _____

List Type/Date _____

Delivered a child in last 3 years . Yes ___ No ___

Are you pregnant? Yes ___ No ___

Do you desire to become pregnant? . Yes ___ No ___

Have you taken antibiotics? . . . Yes ___ No ___
When: _____ For how long a period? _____

Have you taken Cortisone or used Cortisone
creams in last 2 years? Yes ___ No ___

Are you a vegetarian? (no flesh products) Y ___ No ___

Do you avoid milk products? . Yes ___ No ___

Do you avoid sunshine? Yes ___ No ___

Ounces of water you drink per day? _____

Do you like sweets? Yes ___ No ___

Do you take aspirin or ibuprofen type products? Y ___ No ___

Do you take antacids? Yes ___ No ___

List specific pains, complaints, problems and
areas that you would like to address: _____

List operations and dates: _____

List diagnosed illnesses and dates: _____

List vitamins and food supplements; _____

AUTISM SPECTRUM DISORDER CLINICAL TRIAL

ASD Caregiver Checklist for ASD Medical Food Clinical Trial – Monthly Reporting Form

Caregiver to Evaluate Each Symptom/Factor on a 1 to 5 scale*:

- 1 – Not a significant factor, or no improvement in symptom
- 2 – Very Minor factor, or very slight improvement in symptom
- 3 – Minor factor, or slight improvement in symptom
- 4 – Significant factor, or significant improvement in symptom
- 5 – Very significant factor, or very significant improvement in symptom

I. Social communication / interaction behaviors may include:

- 10. Making little or inconsistent eye contact
- 11. Tending not to look at or listen to people
- 12. Rarely sharing enjoyment of objects or activities by pointing or showing things to others
- 13. Failing to, or being slow to, respond to someone calling their name or to other verbal attempts to gain attention
- 14. Having difficulties with the back and forth of conversation
- 15. Often talking at length about a favorite subject without noticing that others are not interested or without giving others a chance to respond
- 16. Having facial expressions, movements, and gestures that do not match what is being said
- 17. Having an unusual tone of voice that may sound sing-song or flat and robot-like
- 18. Having trouble understanding another person's point of view or being unable to predict or understand other people's actions

II. Restrictive / repetitive behaviors may include:

- 6. Repeating certain behaviors or having unusual behaviors. For example, repeating words or phrases, a behavior called *echolalia*
- 7. Having a lasting intense interest in certain topics, such as numbers, details, or facts
- 8. Having overly focused interests, such as with moving objects or parts of objects
- 9. Getting upset by slight changes in a routine
- 10. Being more or less sensitive than other people to sensory input, such as light, noise, clothing, or temperature

III. People with ASD may also experience sleep problems and irritability. Although people with ASD experience many challenges, they may also have much strength, including:

- 4. Being able to learn things in detail and remember information for long periods of time
- 5. Being strong visual and auditory learners
- 6. Excelling in math, science, music, or art

Date: _____

Number of Months on Program: _____

Caregiver Comments

* Symptoms primarily from: <https://www.nimh.nih.gov/health/topics/autism-spectrum-disorders-asd/index.shtml>