Memorandum

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

20 August 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 Principle 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 Crowd Funding by the Institute for health Research. You may contribute to the Trial with any debit or credit card here: **PayPal.me**

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

Sincerely,
Ab Boonswng
Ab Boonswang MD

AMARANTH LIFE SCIENCES PHARMACEUTICAL, INC
AUTISM SPECTRUM DISORDER (ASD) CLINICAL TRIAL
PARTICIPANT INFORMATION FORM
Dr. Narongsak "Dr. Ab" Boonswang
Principle 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: Date:
Address: Phone:

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

Informed Consent and Release

1. The undersigned understands that the Principle 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 <u>not</u> 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).**

<u>The AMARANTH ASD MEDICAL FOOD CLINICAL TRIAL IS FOR RESEARCH PURPOSES ONLY.</u>

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 <u>treat</u> 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, <u>with personal identification removed</u> (anonymous data), for research and educational purposes.**

Dated: _____, 200___.

Signature of Participant or Authorized Caregiver:

_____
Name:

Witness:

_____
Name:

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

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: _____ BASIL BODY TEMPERATURE _____
Under arm 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 .

[ ] (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)

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:_____
_____

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 antiacids? . . . . 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;
_____

Other Information Health Care Providers should know about you:

_____

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

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

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15. [ ] Often talking at length about a favorite subject without noticing that others are not interested or without giving others a chance to respond
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