AUTISM SPECTRUM THERAPY PROTOCOL

AST Research Protocol

This Research Protocol (Protocol) discusses in detail how the Principal Investigator (herein PI) plans to carry out the Research, how Researchers will analyze the data that Researchers collect, and what Researchers plan to do with the results. This protocol follows the Institute for Health Research IRB Guidelines – www.InHeRe.org

[1] Introduction and Background

[1] Title of Study: **Autism Spectrum Therapy (AST)**
[2] Goal or Goals of Study: **Verification of The "MEDICAL MANNA™ THRIVE MEDICAL FOOD FOR CLINICAL MANAGEMENT OF AUTISM SPECTRUM DISORDER (ASD)"**
[3] Method of Study (Summary): **Administration of "Medical Manna" Medical Food to patients diagnosed with Autism Spectrum Disorders.**

☐ This Research is necessary or important for human health or wellness. It involves the following human health or wellness concern: **the autism spectrum disorder crisis.**

Relevant research background includes:

1. The Principle Investigator (PI) is **Narongsak "Dr. Ab" Boonswang, MD**
   Expertise of the PI is: **Licensed Physician**

   [1] Education: **Temple University School of Medicine**
   [2] Degrees Held: **MD**
   [3] Practice: **Thoracic Surgeon**
   [4] Disclosure of Relevant Commercial Interests: N/A

2. Relevant previous non-commercial research includes: N/A
3. Formula Provider: **AMARANTH LIFE SCIENCES PHARMACEUTICAL, INC.**

☐ The positive impact of the Research will be an improvement in the health or wellness of relevant populations, or an increase in scientific knowledge relevant to the health or wellness concerns of such persons.

[2] Study Design & Phases

☐ The following is a description of the study design, sequence, and timing of all study procedures that will be performed:

Study Design: **One Year Clinical Study of diagnosed autism spectrum population members.**

Sequence and Timing of Study Procedures: **After diagnosis and Informed Consent.**

The following screening, intervention, and follow-up will be implemented:

[A] Clinical Study: **Six drops of Medical Food, three times daily, held under tongue for 60 seconds and swallowed, to be given by caregivers. Duration: up to One Year.**

[B] Analysis of Pilot Study: **by caregivers for autism spectrum symptom improvement, through an on-line caregiver reporting system, based on a standard "1 to 5" evaluation of standard ASD symptoms. Caregiver reports to be scored and evaluated in double-blind statistical analysis. See attached Exhibit A.**

[C] Screening of Subjects for Study: **diagnosed with autism spectrum disorder**

☐ The Study Procedures will NOT differ from standard care or procedures (e.g., medical, psychological, educational, etc.).

☐ Any deception (including placebo) or withholding of complete information is NOT required.

☐ The study will take place at the following location(s): Florida and elsewhere

☐ A letter of approval and cooperation from each participating site is required by this Protocol.

[3] Participants

☐ The nature of the research, as set forth in this Protocol, requires and justifies using the participant population in the manner set forth in the above Study Design.

☐ The approximate number and ages for the control and experimental groups are:

Number of Persons, Total	Age Range	Other Relevant Characteristics
1,000	**Full**	**Prior ASD Diagnosis**

☐ The expected gender and minority representation of the participant population should mirror that of the general population.

☐ The criteria for selection for each participant group is: **diagnosed AS disorder.**

☐ The exclusion criteria for each participant group is: medically inappropriate individual, due to existing condition or other medical contraindication.

☐ The primary source for participants is expected to be: **Clinic or medical practice.**

☐ The participants will be approached by the PI and associates or agents through various means of communication, including personal contact by the PI and others. All reasonable steps will be taken to avoid coercion and protect privacy.

☐ If participants will be charged for any study procedures or substances, set forth here: N/A

[4] Risks and Benefits

- The following is the nature and amount of risk of injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs, and devices as understood by PI: **no allergic or adverse reactions expected**.

  The amount of risk the community may be subjected to: **none expected**.

- All reasonable due care will be used to minimize risks and maximize benefits.
- The PI and associates will engage in a continuing reassessment of the balance between risks and benefits and report any doubtful changes to the IHR IRB
- Data and safety monitoring will be a primary responsibility of the PI.
- The expected benefits for individual participants, the community, and society include: **improvement in autism spectrum disorder symptoms.**

[5] Adverse Effects

- Any adverse effects or events will be handled in accordance with normal medical procedures. If a dietary supplement is involved in a serious adverse event, a proper report under the FDA AER System will be filed forthwith on FDA Medwatch Form 3500A: http://www.fda.gov/medwatch/SAFETY/3500A.pdf . A "serious adverse event" is defined by law as: "The term "serious adverse event" is an adverse event that-- (A) results in-- (i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (v) a congenital anomaly or birth defect; or (B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A)."

- The expected facilities and equipment are adequate to handle possible adverse effects.
- The PI and sponsoring entity will be financially responsible for treatment of physical injuries resulting from study procedures. The IHR IRB is not responsible for such financial requirements.

[6] Confidentiality of Research Data

- Prior to publication the PI will take care that all data will be anonymous (no possible link to identifiers).
- If identifiable data is maintained it will be coded and the key to the code will be kept separate from the data.
- Except as required by law and permitted under HIPPA, no other agency or individual will have access to identifiable data.
- All reasonable steps will be taken to protect data, such as: computer with restricted access, locked files, etc.

[7] Informed Consent Forms

- The Informed Consent form shall be in writing. [See IHR IRB format for Informed Consent.] Informed Consent shall disclose expected term of the study and shall include a provision providing for method to leave the study.

[8] Drugs, Substances, and Devices

- All *Non-Investigational Drugs* or other substances (including dietary ingredients and HPUS homeopathic dilutions) that will be used during the research, including the name, source, serving, and method of administration (lawful substances): **"Medical Manna" Medical Food consisting of ethically harvested, after healthy birth, ovine placenta, colloidal gold, silver, platinum and a carrying oil, such as Sacha Inchi.**
- All *Investigational Drugs or Substances* (including New Dietary Ingredient (NDI) and non-HPUS homeopathic dilutions) to be used in the study, if any, including the name, source, dose, method of administration, IND number, and phase of testing. (INDs are to be registered with the appropriate institutional pharmacy): **None.**
- Attached is a List of all *Investigational or Other Devices or Techniques* to be used, if any, including the name, source, description of purpose, method, and Food and Drug Administration IDE number (if any), and explain why the device qualifies as a Non-Significant Risk: None.

[9] Additional Information

- There are no materials with potential radiation risk (e.g., X-rays and radioisotopes).
- We will not use materials with potential radiation risk and are not subject to an annual review by a Radiation Safety Committee.
- Participant medical, academic, or other personal records that will be used include: medical history, addiction diagnosis.
- If required by the Study Design and Protocol, above, the type of audio-visual recordings, tape recordings, or photographs that will be made are: none.
- All scientific instruments used will be tested at regular intervals by or under the immediate direction of the PI
- The data collected will be analyzed by or under PI supervision. The data analysis protocol is: effectiveness of addiction disengagement a lack of return to addictive behavior.
- PI or sponsor should have relevant insurance coverage.

The PI expects to prepare and submit clinical trial notes, papers and reports to peer reviewed and other publications based on the IRB approved Research Protocol and the outcome of the Research.

# # #

EXHIBIT A: ASD Caregiver Checklist for ASD Medical Food 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