Complementary and Alternative Medicine in Treating Autism Spectrum Disorders

Request for Applications

Introduction

Although medical care in the United States is increasingly driven by evidence-based practice, societal pressure for tolerance and incorporation of complementary and alternative forms of health care is significant. Many children (estimates vary from 50% to 75%) with autism spectrum disorders are treated with some form of complementary and alternative intervention, and approximately 1/3 of these are being so treated at the time of diagnostic evaluation.

Parents of children with autism are often dissatisfied with their pediatricians’ lack of knowledge about complementary and alternative treatments. Families desire evidence with which they can judge intervention choices, providers want to determine what interventions are safe and effective, and funding sources of care want to know the potential public health effects of such interventions. All treatments should be held to the same scrutiny.

The goal of this initiative is to identify and evaluate evidence-based integrative therapies and novel, untested treatment applications for autism spectrum disorders that include complementary and alternative forms of health care. Therapies and treatments should be clearly defined so as to enable replications or expansions of initial studies. Areas of special interest include but are not limited to biomedical interventions such as dietary treatments, nutritional supplements, among others and non-biomedical interventions such as sensory integration therapies and others.

Awards

Autism Speaks will make a limited number of research awards based on merit. An amount not to exceed 10% (inclusive) of the total award shall be used for Sponsoring Institution’s indirect (overhead) costs. All awards are one-time, non-renewable research grants.

- Pilot Study Awards for proposals to establish “proof of concept” and develop preliminary data necessary to prepare and submit a competitive research grant application to a major federal funding agency (e.g., NIH, NSF, CDC, etc.) or its equivalent, will be for a maximum of $100,000 per year for one or two years.
- Research Awards for mature proposals including clinical trials will be for a maximum of $150,000 per year for three years.

Eligibility

Investigators holding full or part-time faculty appointments, professional affiliations or equivalent at accredited academic, medical, osteopathic, chiropractic, research or educational institutions are eligible to apply. Applications will NOT be accepted from individuals or proprietary organizations to support the research and development of products or treatments for profit. Each application is restricted to one type of project only – pilot study or research award.
**Letter of Intent**

The applicant must first submit a Letter of Intent (LOI) through the Autism Speaks Grants Administration web site that includes the following information:

a. A concise description of the proposed project including: the type of project (pilot or research), specific aims, methods and expected results.

b. A clear justification for the relevance and potential significance of the project to understanding the treatment, prevention or cure of autism spectrum disorders.

c. Names, titles and institutional affiliations of active collaborators/co-investigators in addition to the PI (excludes consultants, postdoctoral fellows, students and technicians).

The Letter of Intent cannot exceed 2 pages including references. In addition, the LOI field requires that the applicant provide the following information at the time of submission: key word selections, proposal title, number of years requested, and RFA to which the PI is responding. Please refer to the Autism Speaks Grants Administration System for more detailed instructions.

Only applicants whose Letters of Intent are approved by Autism Speaks will be invited to submit full proposals. Applicants whose Letter of Intent are approved will be invited to participate in a “webinar” to discuss the application and review process as well as topics relevant to the preparation and submission of a research application in response to this solicitation, such as common challenges in study design. These information sessions will be held in late October or early November.

An invited proposal cannot deviate significantly from the project description in its approved Letter of Intent. Proposals received without first obtaining an approved LOI will be returned without review. Autism Speaks also reserves the right to return without review any proposal that in its judgment is not in compliance with its rules and procedures for proposal preparation and submission, is not responsive to its research goals, or exceeds its funding limits or available resources.

**Proposal Preparation**

Proposals should be written in 11 point Arial font. Use of smaller or difficult to read font may result in the proposal being returned without review. Please refer to the Autism Speaks Grants Administration System for more detailed instructions.

A typical research proposal will include the following sections:

a. **Scientific/Technical Abstract** (maximum 1 page) and **Key Words**: must be intelligible to a knowledgeable professional peer, and describe the project goal(s) and/or hypothesis, specific aims, research methods, expected results and significance/relevance.

b. **Lay Abstract** (maximum 1 page): must be intelligible to a knowledgeable lay person and describe the project goal(s), general means, expected results and their significance/relevance to the treatment, prevention or cure of autism spectrum disorders.

c. **Research Plan** (10 pages maximum for Pilot Study and 15 pages maximum for Research Award):

   1. **Background**: Describe the historical development and existing empirical support for the integrative therapy or novel treatment application including:

      a. A detailed description of the integrative therapy or novel treatment application (supporting materials should be submitted in the appendix and referenced in the research plan).

      b. Explanation and justification of the case ascertainment or diagnostic parameters.
c. Justification for the appropriateness of the integrative therapy or novel treatment application for the target population.

d. A description of how the integrative therapy or novel treatment application will address the needs of participating children and families, including specific functional outcomes targeted.

2. Study Design: Study participants should be from carefully selected populations and the selection criteria described and justified. Describe: the sampling strategy; implementation and evaluation methods; assessment of the therapeutic benefit; monitoring and reporting of side effects and toxicity; criteria and decision making process for suspending or ending the study prior to completion; the validation of the selected outcomes measures; assessment of child and family outcomes (including treatment acceptability by families); ecological validity of the treatment outcomes; the nature and relevance of control groups (including the use of historical or "off-site" control groups evaluated using the same methods but without the treatment component; the use of an historical control group should be justified) and precautions against bias in the study design and interpretation of results. Describe the feasibility of achieving study objectives within funding period (including sample availability and readiness to implement the proposed intervention). Describe the development and role of a Trial Steering Committee. Address any ethical issues implicit in study design.

3. Statistical Analysis: Describe proposed statistical analyses including how sample size will be determined and a power analysis to show that the sample size will produce statistically significant results.

4. Other Treatments: Describe any potential confounding factors or combined interventions (diet, medication, etc.) that parents are using in addition to and outside of the control of the treatment protocol, and their potential or known impact on the treatment protocol.

d. Bibliography with complete literature citations including titles and all authors.

e. Budget for each year of the project and a cumulative budget; the budget may include:

1. Personnel Costs (not to exceed the percent effort committed to the proposed project)
   a. Principal Investigator and/or Co-Investigator salaries and benefits (allowed for research proposals only; NOT ALLOWED for pilot studies).
   b. Technical support salaries and benefits.
   c. Postdoctoral fellow stipend and benefits.
   d. Graduate student stipend benefits (NOTE: Tuition reimbursement is not allowed).

2. Project Costs
   a. Research supplies, services and related expenses.
   b. Essential equipment not to exceed $15,000 per year or $30,000 total (allowed for research proposals only; NOT ALLOWED for pilot studies). A vendor estimate is required for a single item of equipment costing more than $5,000.
   c. Travel to professional meetings.
   d. Data analysis and publication costs.

- Budget justification: Justify personnel costs, project-dedicated resources, services and equipment and any unusually costly expenses or travel.
- Description of relevant facilities and necessary on-site and off-site resources.
- Biographical Sketches of the Principal Investigator and named Co-Investigators in NIH format, not to exceed 3 pages each; indicate education, professional
appointments and honors, total number of peer-reviewed publications, and complete citations (including title) of publications relevant to the proposed research.

- Current and Pending Support: indicate funding source, total award amount, award duration (inclusive dates) and project title; clearly explain any overlap with the proposed research including the extent to which the projects are redundant or complementary.

- Human Subjects Certifications must be documented with a copy of an official letter of approval (or equivalent for non-US applicants), which identifies the Principal Investigator, project title and date of approval, and is signed by the Review Committee Chair or equivalent responsible institutional/government official. Prior certification for another project cannot be substituted, but can be officially amended to include the proposed project (identified by project title).

**IMPORTANT:** IRB (or equivalent ethical) certification is NOT required to submit an application; however, IRB (or equivalent ethical) certification must be submitted as soon as possible following official notification of an award. Autism Speaks will NOT issue the first funding increment of a grant until this certification is received. Rules governing human subjects (IRB) certifications for both US and non-US institutions can be found at: [http://grants.autismspeaks.org/research/tandc.asp](http://grants.autismspeaks.org/research/tandc.asp).

- Letters of Collaboration or Agreement
- Appendices: Critical photographs or instrument descriptions requiring special formatting and other essential background material can be submitted as pdf files and referenced in the Research Plan. A maximum of 3 peer reviewed research publications (including manuscripts under review or accepted for publication) will be accepted; however, manuscripts not yet accepted for review, review articles, book chapters, popular press articles and meeting abstracts will NOT be accepted. WARNING! Appendix publications are provided as a courtesy to the reviewers who are under no obligation to read or consult them in evaluating a proposal.

Submission of Letters of Intent and Proposals
Only Letters of Intent and proposals submitted through the Autism Speaks Grants Administration System at [http://grants.autismspeaks.org/research/login.asp](http://grants.autismspeaks.org/research/login.asp) will be accepted for review. Applicants should refer to the Grants Administration web site for specific requirements and instructions about electronic LOI and proposal submission. A successful electronic LOI or proposal submission will be confirmed by a system generated email notification to the applicant. Letters of Intent or proposals submitted by regular mail or by email will be returned without review. **Letters of Intent are due on September 28, 2007. Proposals are due on February 15, 2008.**

**IMPORTANT!** Letters of Intent and proposals will NOT BE ACCEPTED after their due dates unless prior permission is obtained, and only for exceptional circumstances (e.g., child birth, serious illness or death in the family, natural disaster). It is the applicant’s responsibility to insure that both the Letter of Intent and Proposal are in compliance with the policies and procedures prescribed in the RFA. Autism Speaks reserves the right to return without review any Letter of Intent or Proposal found to be not in compliance with the policies and procedures prescribed on the RFA at any time during the application and review process.

Review and Selection
The peer review panel will meet in March 2008. Funding selections and notification of awardees will be made in April 2008, with an expected award start date on or about May 2008.
Payment of Awards
Awards will be paid annually and will be contingent upon registration in the Autism Speaks Grants Administration System of an official authorized to act for the institution receiving the award, and upon acceptance of the Autism Speaks award terms and conditions as described at http://grants.autismspeaks.org/research/tandc.asp including receipt of all required certifications.

Funding for award years 02 and 03 will be contingent upon submission by the principal investigator of a satisfactory annual project progress report, and a financial statement showing expended and unexpended funds. Unexpended funds in excess of 25% of the annual award must be satisfactorily explained before those funds can be rolled over into the next year of the grant. In addition, an investigator may request a one-time, six-month non-cost extension from the termination date of the award in order to complete necessary work (including data analysis and preparation/submission of manuscripts for publication).

Please address questions about proposal submission using the web-based Grants Administration System to Ms. Susan Kravitz, Grants Administrator by telephone at 609-228-7323 or by email at: skravitz@autismspeaks.org. All other questions (including eligibility to apply) should be addressed to Dr. Charles D. Liarakos, Director of Scientific Review at: cliarakos@autismspeaks.org.