



## Special Interventions in Autism Spectrum Disorders

### Request For Applications

#### Introduction

Autism Speaks recognises the urgent need to develop effective interventions to treat autism and autism spectrum disorders which could target the core and domain specific features of autism and also associated behavioural problems. Applications are encouraged both from scientists already focusing on autism and from those new to the field. All proposals must have direct and immediate relevance to autism and related disorders.

Proposals should seek to accomplish one or more of the following objectives:

- Evaluate the efficacy or therapeutic benefit of interventions in children and adults diagnosed with autism and autism spectrum disorders.
- Evaluate the safety of the use of interventions in children and adults diagnosed with autism and autism spectrum disorders.
- Compare different interventions.

This initiative is aimed at both behavioural and non-behavioural interventions including educational, psychological, physiological and technological interventions. Examples include but are not limited to, music, play, speech, language and communication based therapies, biofeedback, and vagal and transcranial magnetic stimulation. The goal of the Pilot level awards is to provide robust and reliable pilot data and to identify strong interventions that can be evaluated in broader-scale clinical programs. Therefore, study design should be clearly defined so as to enable replications or expansions of the initial studies.

#### 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 develop **preliminary results** that identify strong interventions for subsequent larger studies 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, research or educational institutions are eligible to apply. Educators, optometrists, audiologists, speech pathologists holding advanced degrees (e.g., Ed.D. or Masters Degree) are welcomed to apply.

Applicants are restricted to one proposal per review cycle as Principal Investigator. Applications will NOT be accepted from individuals or proprietary organizations to support the research and development of products for profit. Each application is restricted to one type of project only – pilot study or research proposal.

### Letter of Intent

The applicant must first submit a Letter of Intent 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 as to the relevance for advancing the state of knowledge in the treatment of autism and autism spectrum disorders and, for the Pilot level awards, the potential significance of the study in providing robust pilot efficacy and safety data on the intervention used in individuals diagnosed with autism and 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. 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 (which can be found on [www.autismspeaks.org](http://www.autismspeaks.org)), or exceeds its funding limits or available resources.

### Proposal Preparation

A proposal cannot deviate significantly from the project description in the Letter of Intent. Proposals should be written in 11 point Arial font. Use of smaller or difficult to read fonts 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:

- 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
- 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
- Research Plan (10 pages maximum for Pilot Study and 15 pages maximum for Research Award):
  1. Background: Describe the theoretical framework, initial development and existing empirical support for the intervention including:
    - a. The background for the study design (supporting materials should be submitted in the appendix and referenced in the research plan);
    - b. The expected therapeutic benefit(s) and the likelihood that the benefit(s) will outweigh any negative side effects;
    - c. How the expected benefit(s) of the intervention will address the needs of participating children and families, including specific functional outcomes;

- d. How strong positive findings could be further evaluated in larger studies;
  - e. The use of any biomarkers.
- 2. Study Design: Describe and justify: the inclusion/exclusion criteria, 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 intervention acceptability by families); 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 a timeline for achieving the specific aims and 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 intervention.
- Bibliography with complete literature citations including titles and all authors
- Budget for each year of the project and a cumulative budget. The budget may include:
- Personnel Costs (not to exceed the percent effort committed to the proposed project)
  - Principal Investigator and/or Co-Investigator salaries and benefits (allowed for research proposals only; NOT ALLOWED for pilot studies)
  - Technical support salaries and benefits
  - Postdoctoral fellow stipend and benefits
  - Graduate student stipend benefits (NOTE: Tuition reimbursement is not allowed.)
- Project Costs
  - Research supplies, services and related expenses
  - Essential equipment not to exceed \$15,000 per year or \$30,000 total. A vendor estimate is required for a single item of equipment costing more than \$5000.
  - Travel to professional meetings
  - 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, complete citations (including title) of publications relevant to the proposed research and briefly describe currently funded research projects.

- 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>.
- 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 electronically submitted through the Autism Speaks Grants Administration System will be accepted for review:

<http://grants.autismspeaks.org/research/login.asp>. Letters of Intent and 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!** Proposals will NOT BE ACCEPTED after the due date 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 the proposal is in compliance with the policies and procedures prescribed in the RFA. Autism Speaks reserves the right to return without review any 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 in 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](mailto: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](mailto:cliarakos@autismspeaks.org).