



**Request for Applications**  
**Treatment Research**  
**2009 Cycle**

**I. Introduction**

Autism Speaks invites grant applications to conduct *innovative* clinical studies of evidence-based therapies and novel treatment approaches for children and adults with Autism Spectrum Disorders (ASD). These may include complementary and alternative forms of health care; pharmacological and/or behavioral treatments; and evaluation of the efficacy, safety or therapeutic benefits of interventions.

*Proposals on the following topics are particularly encouraged:* Mediators and moderators of response to treatment; biomarkers that are linked to response to treatment; studies that incorporate biological outcome measures, such as EEG/ERP, fMRI; translational efforts derived from animal models of recovery; novel treatments that target core autism symptoms; infant/toddler interventions; treatments for adolescents and adults; commonly used treatments that lack efficacy/safety data; treatments that address associated medical conditions, such as sleep, metabolic, and GI problems; service delivery and dissemination research aimed at identifying factors that promote or impede adoption of evidence-based clinical practices.

*Note:* The relevance of the proposed research to ASD must be explicitly stated.

**II. Awards**

Autism Speaks will make a limited number of treatment research grants determined by its available financial resources. Each research grants will be for a period of up to three years in an amount not to exceed \$100,000 per year. An amount not to exceed 10% of direct costs may be used for Sponsoring Institution's indirect (overhead) costs. The total award including indirect costs cannot exceed the annual maximum award allowed.

**III. 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.

Applicants are restricted to one proposal per review cycle as Principal Investigator.

#### **IV. Submission Requirements**

##### Electronic Proposal Submission: General Guidelines

- a. The applicant **must** apply through the Autism Speaks Grants Administration website at <http://grants.autismspeaks.org/research/login.asp>. Letters of Intent and Proposals must be submitted electronically in order to be accepted for review and considered for funding. LOI's and Proposals submitted in any other manner (e.g. by regular mail or by email) will be returned without review. The applicant will receive confirmation of a successful electronic submission via system-generated email.
- b. Investigators new to the Autism Speaks submission process:
  1. All new investigators are encouraged to review the layout and format of the grants administration system at least one month prior to the application deadline.
  2. Each new applicant/investigator must first register with the grants system at [http://grants.autismspeaks.org/research/signup\\_form.asp](http://grants.autismspeaks.org/research/signup_form.asp). Please be sure to choose the role "**Investigator**". Please fill out the form completely.
- c. **Mandatory Letters of Intent (LOI) are due no later than December 1, 2008. Proposals are due no later than January 20, 2009 at 11:59 PM (EST).**
  - i. One update of pilot data up to two pages in length will be accepted on or before February 28, 2009. This document may not redesign the proposal in any way. The format must follow the specifications in section IV.d. below. The update should be emailed to Joan New at [jnew@autismspeaks.org](mailto:jnew@autismspeaks.org).
  - ii. Autism Speaks reserves the right to return without review any Letter of Intent or Proposal found to be not in compliance with the policies, procedures, and research priorities prescribed in the RFA at any time during the application and review process.
- d. Information and Formatting
  - i. Text should be 11 point Arial, single spaced, with 1" margins.
  - ii. **Applications with any sections that exceed the word or page limits will not be reviewed.**
  - iii. Guidance on where to upload each of the required elements is provided in the outline below.

#### **V. Registering Your Letter of Intent**

Click on "Begin New Application".

- i. Enter the title of your project (less than 128 characters, spaces included)
- ii. Select "Treatment Research 2009" (dropdown menu for Award Type) and choose the number of years.
- iii. Choose up to two Subject Area Keywords and up to four Methodology Keywords (for a maximum of five). One keyword each is required.
- iv. Upload your Letter of Intent (see below for guidelines).
- v. To complete this section: Click on "Submit Letter of Intent" at the bottom of the page.

##### Letter of Intent Guidelines:

The Letter of Intent cannot exceed 2 pages, and must include the following information:

- i. A concise description of the proposed project including: specific aims, methods and expected results.

- ii. A clear justification for the relevance and potential significance of the project to understanding the causes, diagnosis, treatment, prevention or cure of Autism Spectrum Disorders.
- iii. Names, titles and institutional affiliations of active collaborators/co-investigators in addition to the PI (excludes consultants, postdoctoral fellows, students and technicians)

Upon submitting the Letter of Intent, the applicant will receive a confirmation e-mail and instructions on when they may begin the full proposal application. The proposal cannot deviate significantly from the project description in its approved Letter of Intent.

## **VI. Uploading Your Proposal**

At the prescribed time, you will be able to begin your proposal. Log in and select your application. You will now have more menu options.

### **A. Institutional Info and Grant Contact**

- i. "View" the Responsible Official (RO) to assign this role. The Responsible Official is someone from the applicant's institution, other than the applicant, who can endorse the proposal.
- ii. Look up your RO's e-mail address. If your RO is not in the database, click on "Save Selected Contact" to add their record.

### **B. Scientific Abstract (250 words max)**

- i. The abstract must describe the project goal(s) and/or hypothesis, specific aims, research methods, expected results and significance/relevance.
- ii. This is uploaded in the system under "Keywords and Abstract".

### **C. Layperson Abstract (250 words max)**

- i. The layperson abstract must be easily intelligible to a knowledgeable lay person or non-expert.
- ii. This is uploaded in the grant system under "Keywords and Abstract"

### **D. Research Plan (12 pages max). This should include:**

**Impact and Relevance**  
**Innovation**  
**Research Strategy**  
**Investigators' Qualifications**  
**Environment**

The research plan should address the evaluation criteria in section VIII.

This should be one document, uploaded to "Experimental Plan and Methods" under "Research Plan".

You may include a maximum of two pages of relevant images, figures and graphics, using two of the additional upload fields below "Experimental Plan". Images uploaded in these fields will not be counted towards the 12 page maximum limit.

### **E. Bibliography with complete literature citations including titles and all authors. This is uploaded under "Literature Cited - Bibliography".**

- F. Detailed budget for each year. **Applicants should ensure that their budget is in accordance with the RFA. Budgets which exceed the maximum amount will not be accepted by the grants system.** The budget may include:
- i. Personnel Costs (not to exceed the percent effort committed to the proposed project)
    1. Principal Investigator and/or Co-Investigator salaries and benefits
    2. Technical research assistant salary and benefits
    3. Graduate student or postdoctoral fellow stipend and benefits (NOTE: Tuition reimbursement is not allowed).
  - ii. Research supplies, services and related expenses
  - iii. 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.
  - iv. Consultants
  - v. Travel to professional meetings
  - vi. Publication and data analysis costs
  - vii. Overhead: An amount not to exceed 10% of direct costs may be given to the Sponsoring Institution for indirect (overhead) costs in addition to the grant amount.
  - viii. Collaborations: If you are collaborating with a second site, put their total amount in "Other" and upload their line-item budget under "Budget Subcontract". Total indirect costs for both sites cannot exceed the maximum allowed.
  - ix. Note: All budget fields must be filled in. If a line item does not apply, please write "0" in the amount, and "N/A" in the description field.
- G. Budget Justification (4 pages max)
- i. The budget justification should address each category requested for each year.
  - ii. The budget justification is uploaded in the "Budget" section.
  - iii. If your justification document covers all years requested in the budget, you can upload it once.
- H. Resources and research environment (1 page max)
- i. Describe the resources and environment that will support the successful completion of the project.
  - ii. If the project will be utilizing existing samples and/or collecting samples, it should be specified how and when they will be used and shared with the autism community following the end of the project.
  - iii. This should be uploaded under "Facilities & Resources".
- I. Letters of Collaboration, if needed. These are uploaded under "Collaborative Arrangements", under the "Other Attachments" section.
- J. Biographical Sketches of the Principal Investigator and named Co-Investigators in NIH format (4 pages max each)
- i. Indicate education, complete citations (including title) of publications relevant to the proposed research and briefly describe currently funded research projects (especially clinical and research experience with pharmacological or other treatment in mental health disorders)
  - ii. Submit these under the "Biographical Sketches" section of "Other Attachments"
- K. Current and pending grant support.
- i. 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

- ii. Submit in “Current and Pending Support” under “Other Attachments”.

#### L. Appendices

- i. Publications or other supporting files that are relevant to the application must be referenced in the research plan and may be uploaded to “Exhibits” in the “Other Attachments” section.
- ii. A maximum of 2 peer reviewed research publications (including manuscripts 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. Upload these in the “Publication reprints” in the “Other Attachments” section.
- iii. Appendix publications are provided as a courtesy to the reviewers who are under no obligation to read or consult them in evaluating a proposal.

### **VII. Endorsing & Submitting the Proposal**

Before the proposal can be submitted online, it needs to be endorsed by your institution.

- i. Enter a Responsible Official in “Institutional Info & Contacts”. A Responsible Official (RO) is someone at the applicant organization, other than the applicant/PI, who can endorse the proposal. On the RO line, click “View”. Enter in the contact’s email address and click “Look Up E-mail”. If they are not already in the system, click on Save Selected Contact and fill out their information.
- ii. Once you have finished uploading files for your proposal, click on “E-Mail Responsible Official” in “Approvals & Status”. The RO will receive an email notification with instructions on endorsing your proposal. It is recommended you call or email this person to ensure they received this notification.
- iii. The RO will be instructed to review the budget and proposal, and endorse in “Approvals & Status”. You will receive an email that endorsement is complete.
- iv. You can now go into “Preview and Submit Proposal” to complete your submission.

### **VIII. Review Process and Evaluation Criteria**

Autism Speaks is committed to efficient, fair and expert review and funding of meritorious proposals that are relevant to the mission of Autism Speaks. Review of scientific merit is provided by a group of highly accomplished researchers from the Autism Speaks Scientific Advisory Board with additional expertise, as needed, from ad hoc expert reviewers in the specific research areas of the proposals.

*Proposals are evaluated using the following criteria:*

#### **Impact and Relevance**

The mission of Autism Speaks’ science program is to fund research that will accelerate the discovery of the causes, treatment, and prevention of autism spectrum disorder. The degree to which the proposal directly addresses the mission of Autism Speaks’ is a key evaluation criterion. Does the proposal address an important autism-specific problem that is relevant to Autism Speaks’ mission? How will testing the proposed hypothesis, undertaking the proposed endeavor, or solving the proposed problem have impact in terms of the mission? Will the proposed research and expected results contribute new knowledge or methods to advance the goal(s) of discovering the causes, diagnosis, treatment and/or cure of autism spectrum disorders?

### **Innovation**

Does the proposal develop innovative and creative ideas or methods of research, diagnosis or treatment? Does the project propose to develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area? Does the proposal challenge an existing paradigm or practice? Does the proposal encompass ideas or methods that have not been previously utilized in the field or have not been applied in the way that is proposed?

### **Research Strategy**

Is the project proposed well-designed? Are the key components of the sample, methods, and data analytic approaches well-described and reasonable? Are the overall strategy, milestones, and timeline well-reasoned, realistic, and appropriate to the aims of the proposed project? Are potential problem areas acknowledged, alternative tactics considered, and benchmarks for success presented? Is a convincing argument made that the required methods and analyses will be available, developed, and implemented competently, and are these feasible for this research team?

### **Investigators' Qualifications**

Do the investigators have the appropriate training and expertise to conduct the proposed research? Have they demonstrated satisfactory productivity, relative to stage of career, in terms of peer-reviewed publications and other benchmarks in the area of the proposed research? Have necessary collaborations been established and documented with letters of agreement?

### **Environment**

Do the performance sites where the work will be done contribute to the probability of success? Is the scientific environment conducive to the work proposed, in terms of institutional support, physical resources, and clinical and intellectual resources? Will the proposed studies benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Has access to necessary special research equipment, data bases, and/or facilities been appropriately documented with letters of agreement? Does the investigator document access to the appropriate clinical/animal/laboratory resources needed to conduct the proposed study?

### **Submission, Review, & Notification Schedule (subject to change):**

Letter of Intent due:	December 1, 2008
Proposal due:	January 20, 2009
Peer review panels:	April/May, 2009
Notifications:	June, 2009
Grant start date:	July 1, 2009

### **IX. Miscellaneous**

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.

Proposals using post mortem tissue must provide documentation that the necessary tissue is or will be available at the research site at the time of the award. Proposals without proper documentation will be returned without review. Investigators desiring to obtain tissue from the Autism Tissue Program should go to **atportal.org** for information, application instructions and due dates.

The first payment will be contingent upon receipt of the countersigned grant agreement letter and certification of ethics approval, if applicable. Subsequent payments on multiyear grants will be paid annually and will be contingent upon receipt and approval of interim progress and financial reporting. Interim reports are due 10 months after the start of the grant, and final reports are due 2 months after the end of the grant. All payments are contingent upon available funds to Autism Speaks.

Funded researchers also are required to submit or have submitted for them to the National Institutes of Health's PubMed Central database an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. This requirement applies to all grants awarded after December 3, 2008, whether Autism Speaks funds the research in whole or in part.

Autism Speaks reserves the right to make information about funded grants publicly available. Funded research projects may be subject to data and resource sharing requirements.

#### **X. Contacts:**

Please address questions about proposal submission using the web-based Grants Administration System to Joan New, Grants Assistant, [jnew@autismspeaks.org](mailto:jnew@autismspeaks.org) or 609-228-7313. All other questions should be directed to Anita Miller Sostek, Ph.D., Vice President of Scientific Review and Operations, at [anita.sostek@autismspeaks.org](mailto:anita.sostek@autismspeaks.org) or 202-955-3314.