2011 Request for Applications
Treatment Research Grants: Full- and Pilot-Level

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

Letter of Intent due: December 16, 2010
Letter of intent notifications: February 2011
Application due: April 5, 2011
Peer review panels: July 2011
Notifications: October 2011
Earliest Grant start date: November 1, 2011

I. Introduction

Autism Speaks invites both Full- and Pilot-Level Treatment research grant applications to conduct innovative clinical studies of novel interventions for individuals with Autism Spectrum Disorders (ASD) throughout the lifespan. These may include medical, complementary and alternative forms of health care; pharmacological, and/or behavioral/psychosocial interventions; and evaluation of the efficacy, safety or therapeutic benefits of interventions.

For all RFAs, Autism Speaks is focusing on a set of targeted research priorities. All treatment study projects will be required to demonstrate direct relevance to at least one of these targeted research priorities:

1. Discovery of risk factors for autism, especially environmental factors and gene-environment interactions
2. Development of methods for very early detection of ASD risk
3. Understanding the natural course of adult development in ASD, with emphasis on factors related to outcome, medical co-morbidities, and mortality
4. Identification of the molecular pathophysiology of ASD that can inform translational research for drug discovery or development of diagnostic methods
5. Development and evaluation of novel treatments that can address the core symptoms and associated medical (including psychiatric) conditions throughout the lifespan
6. Dissemination of empirically-validated screening, diagnostic and treatment approaches

IMPORTANT: The relevance of the proposed research to ASD and Autism Speaks’ research priority areas must be explicitly described in the Letter of Intent (LOI) and full application.

II. Awards

Autism Speaks will make a limited number of treatment research grants determined by the available financial resources.
<table>
<thead>
<tr>
<th>Type</th>
<th>Duration</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full-level research grant</td>
<td>1-3 years</td>
<td>$150,000/year maximum</td>
</tr>
<tr>
<td>Pilot-level research grant</td>
<td>1-2 years</td>
<td>$60,000/year maximum</td>
</tr>
</tbody>
</table>

An amount not to exceed 10% (inclusive) 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.

Pilot-Level Treatment Awards must satisfy one or more of the following requirements:

- Employ **innovative, novel and/or untested research in biomedical or behavioral treatment approaches**, which if successful, will advance emerging or transforming areas of research on the prevention, treatment, or cure of autism spectrum disorders
- Develop **preliminary data necessary to expand to the level of a trial, develop a research program and/or submit a competitive treatment research grant application to a major funding agency (e.g., NIH, NSF, CDC etc.) or the equivalent**
- Come from **beginning principal investigators** with demonstrated potential for and a commitment to autism research
  - OR
- Come from **established investigators** with expertise and experience in other (non-autism) areas of research that are relevant and will be applied directly to research on autism spectrum disorders

Full-Level Treatment Awards must satisfy the following requirements:

- Build on existing and/or pilot-level feasibility data to further investigate **biomedical or behavioral treatment approaches** that, if successful, will advance emerging or transforming areas of research on the prevention, treatment, or cure of autism spectrum disorders
- Have shown promise in previous research or that are supported by a body of existing research evidence.
- Come from **established principal investigators** with demonstrated potential for and a commitment to autism research

III. Eligibility

Investigators holding full-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.

As Principal Investigator or Co-Investigator, all applicants are restricted to one submission per Treatment review cycle, regardless of whether it is at the Full or Pilot Level. **Multiple submissions will all be returned.**

IV. Submission Requirements

Autism Speaks utilizes a web-based application system for their grant submissions. All applications must be submitted through this system. It is imperative to indicate whether the submission is for the Full- or Pilot-Level Treatment research option.
Please Note:

1. The Principal Investigator must first send an email from their institutional email address to grantadmin@autismspeaks.org indicating their interest to apply, including name, institution, office or lab address and phone #. Access information will be returned by email.

2. Uploaded documents, with the exception of NIH Biosketches, should be 11 point Arial font with 1-inch margins all around. Applications exceeding the specified document limits will not be reviewed.

3. Do not put headers or footers on submitted documents. The grant system places information in the header and footer when the full application PDF is generated. Applicants can check this by using the Print Packet on the LOI or application page.

4. Preferred file type is PDF. If your file exceeds the upload limit, try using the Fax to File tool on the Grant site.

5. Applications received after the deadline will not be accepted unless permission has been previously granted by the Autism Speaks Grants Office and then only due to rare and unavoidable circumstance. There are no exceptions to this rule. All decisions of Autism Speaks in regard to late submissions will be final.

6. It is the applicant’s responsibility to contact their Office of Sponsored Projects (or the equivalent) to identify the Responsible Official (RO) for this application. The Responsible Official will review and submit the final portion of the application. Their submission is their approval of the application on behalf of the institution. The LOI page can be completed and submitted by the applicant. Full applications can only be submitted by the RO. The RO’s name and contact information will be a part of the LOI page.

V. Submitting the Letter of Intent

Log in and click on Start New Application and then choose either 2011 Treatment Pilot-Level or 2011 Treatment Full-Level. The LOI page requires the following and must be complete:

1. Application Title: Enter less than 100 characters, spaces included
2. Select the Autism Speaks' targeted priority which the project is addressing.
3. Short summary of the research topic and how it relates to Autism Speaks' priorities (up to 3000 characters)
4. Biosketch for the PI in the NIH format not to exceed 4 pages
5. Names, emails and institutions of Co-Investigator(s) and significant collaborators
6. The Letter of Intent Narrative – see immediately below
7. A letter, one page maximum, from the institution’s Office of Sponsored Projects (or its equivalent) or the Head of the PI’s Department/School/Division, confirming the PI's eligibility. You must use the form provided on the LOI page. Please refer to section III above.
8. Name and contact information for the Responsible Official from the PI’s institution
**Letter of Intent Narrative Guidelines:**

The LOI Narrative cannot exceed 2 pages, and must include the following information.

- A concise description of the proposed project including: type of Treatment project, specific aims, methods and expected results
- A clear justification for the relevance and potential significance of the project to the targeted priority research areas described above
- The LOI should be specific enough to be screened for scientific merit, fidelity to the purpose of the specific RFA, and relevance to Autism Speaks’ priority research areas.

**IMPORTANT NOTE:** LOIs will be subject to in-depth review. After all LOIs are reviewed, Autism Speaks will send an email indicating approval or disapproval. *Please do not contact the grants staff regarding LOI acceptability.* Applicants with approved LOIs will be permitted to submit a full application. All decisions are final.

**VI. Completing Your Application**

If you are notified that your LOI has been approved, you will be able to begin your application. Log in and select your application.

A. Identify which Autism Speaks’ target research priority is addressed by this application and explain how it is addressed (3500 characters for explanation, spaces included)

B. A Scientific Abstract (up to 2500 characters, spaces included) that must describe the project goal(s) and/or hypothesis, specific aims, research methods, expected results and significance/relevance to Autism Speaks’ targeted research areas as described above.

C. A Layperson Abstract (up to 2500 characters, spaces included) that must be easily intelligible to a knowledgeable, but non-expert, person.

D. Research Plan (10 pages maximum). The research plan should address the evaluation criteria in section IX below. **

   a. Impact in terms of potential to improve the lives of persons struggling with Autism Spectrum Disorders **
   b. Relevance to Autism Speaks’ targeted priority research areas
   c. Innovation – describe how the project is novel, ground-breaking, and has the potential to move the field in new directions
   d. Research Strategy, including specific aims, participant exclusion/inclusion criteria, recruitment strategy, methods and procedures, and statistical analyses to address specific aims
   e. Investigators’ Qualifications – briefly describe (Biosketches must be provided – see J below)
   f. Environment – briefly describe (greater detail should be included in H described below)

**IMPORTANT NOTE:** Impact will also be measured long-term via Autism Speaks’ future surveys on the impact and outcome of the grant (e.g., publications, leveraged grant funding) for at least 3 years after completion of the project. A clear willingness and commitment to respond to all outcomes requests is required for awardees.

E. You may include a maximum of two pages of relevant images, figures and graphics. Images uploaded here will not be counted towards the 10-page limit.
F. Bibliography with complete literature citations including titles and all authors.

G. Download and complete the **Treatment Budget Form**. The budget may include:
   a. Personnel Costs (not to exceed the percent effort committed to the proposed project)
      i. Principal Investigator and/or Co-Investigator salaries and benefits
      ii. Technical research assistant salary and benefits
      iii. Research Assistant or fellow stipends and benefits are allowed (*NOTE: Tuition reimbursement is not allowed*).
   b. Research supplies, services and related expenses
   c. Essential equipment as shown in the table. A vendor estimate is required for a single item of equipment costing more than $5000.

<table>
<thead>
<tr>
<th>Type</th>
<th>Duration</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full-level research grant</td>
<td>1-3 years</td>
<td>$150,000/year maximum</td>
</tr>
<tr>
<td>Pilot-level research grant</td>
<td>1-2 years</td>
<td>$60,000/year maximum</td>
</tr>
</tbody>
</table>

   d. Consultants
   e. Travel to professional meetings
   f. Publication and data analysis costs
   g. Indirect costs: An amount not to exceed 10% of direct costs may be included for the Sponsoring Institution’s indirect (overhead) costs. The total grant cannot exceed $150,000 per year (Full-Scale Research Grant) or $60,000 (Pilot Research Grant).
   h. Collaborations: If you are collaborating with a second site, put their total amount in “Subcontract” and upload their line-item budget under “Budget Subcontract.” Total indirect costs for both sites cannot exceed the maximum allowed.

H. Budget Justification (4 pages max). The budget justification should provide an explanation for all lines in the budget for all years.

I. Resources and research environment (1 page max). Describe the resources and environment that will support the successful completion of the project. 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.

J. Letters of Collaboration, if needed.

K. Biographical Sketches of the Principal Investigator, named Co-Investigators and significant participants in NIH format (4 pages max each). 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).

L. Current and pending grant support. Indicate funding source, total award amount, award duration (inclusive dates) and project title for all investigators and significant collaborators. Financial and substantive overlap will be examined after review.
M. Other supporting files that are relevant to the application must be referenced in the research plan and may be uploaded to “Additional Materials.” Multiple documents should be combined into one file for upload (3 MB maximum).

N. 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. Publication files MUST NOT be locked or protected in any way.

**NOTE:** Supporting files, publications and updates (see VIII) are provided as a courtesy to the reviewers who are not obligated to refer to them in evaluating an application.

**VII. Endorsing & Submitting the Application**

Applications must be submitted electronically using the Autism Speaks Online Grant Administration System. Applications that are late, incomplete, exceed the document limitations, or do not adhere to the required format will not be reviewed. Applications that are faxed or emailed will also not be reviewed.

When an LOI is approved, the Responsible Official named in the LOI will be contacted by Autism Speaks’ grants staff with system access information. When the application is complete, it is the responsibility of the applicant to contact their Responsible Official who must complete the submission. The Responsible Official’s submission of the application signifies their endorsement on behalf of the institution.

Autism Speaks reserves the right to return without review any fellowship application that in its judgment is not in compliance with its rules and procedures for application preparation and submission, is not responsive to its research training goals, or exceeds its funding limits or available resources. It is the responsibility of the applicant to ensure that the application is complete and conforms to the guidelines.

**VIII. Review Process and Evaluation Criteria**

Autism Speaks is committed to efficient, fair and expert review and funding of meritorious applications 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 other researchers in the specific research areas of the applications.

*Applications are evaluated using the following criteria. **Pilot-Level Treatment grants may be more limited in scope will not be expected to have definitive preliminary data.**:

**Impact and Relevance**

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? Specifically, does the application directly address the Autism Speaks’ targeted research areas as described above. To what extent does testing the proposed hypothesis, undertaking the proposed endeavor, or solving the proposed problem have the potential to move the field forward?
Innovation
Does the application 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 application challenge an existing paradigm or practice? Will the project application propose ideas or methods that have not been previously utilized in autism research or have not been applied in the way that is proposed?

Research Strategy
Is the project proposed well designed? For Full-Level Treatment research grants, is there preliminary data available to establish feasibility and support the likelihood of further success? ** Although preliminary data are not required for Pilot-Level research grants, any data submitted may be critiqued. ** Are the key components of the sample, methods, and data analytic approaches well described and reasonable? Does the application present well reasoned, realistic, and appropriate to the strategy, milestones, and timeline of the proposed project? Are potential problem areas acknowledged, alternative tactics considered, and benchmarks for success presented? Will the required methods and analyses will be available and implemented appropriately, and are they feasible for this research team relative to the scope of the proposed project?

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 the 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 application document access to the appropriate clinical/animal/laboratory resources needed to conduct the proposed study?

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.
Applications 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. Applications without proper documentation will be returned without review. Investigators desiring to obtain tissue from the Autism Tissue Program should go to [atpportal.org](http://atpportal.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.

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:**

**Grants Administration/Online Application/Budget Questions:**

Joan New, MBA, Senior Grants Administrator: 609-228-7313; email: jnew@autismspeaks.org

**Application Development:**

Anita Miller Sostek, Ph.D., Vice President, Scientific Review & Operations: 202-955-3314 or 202-384-5882; email: anita.sostek@autismspeaks.org

Michael Rosanoff, MPH, Associate Director, Public Health Research & Scientific Review: 917-475-5067; email: mrosanoff@autismspeaks.org