



## Autism Speaks Suzanne and Bob Wright Trailblazer Award Program 2012 Request for Applications

**Autism Speaks places a high priority on innovation and has designed its new Trailblazer Award to respond quickly to fund highly novel transformative projects.** The Trailblazer Award mechanism will support highly novel “out of the box” autism-relevant research that open new avenues to understanding the causes, diagnosis, subtyping, prevention, treatments, and cure of autism spectrum disorders. The Trailblazer Award mechanism is designed to fund small investigator-initiated **high risk/high impact** projects that are potentially **transformative, paradigm shifting, and/or will overcome significant roadblocks** in autism research **within a 12 month period**. We are seeking projects that may be too risky for regular research mechanisms, including that of Autism Speaks Pilot Study grants.

### The proposed Trailblazer project:

- Must explore a **highly** novel idea or research technique that potentially could have high impact, i.e., have the capacity to change the way we diagnose, subtype, prevent, and/or treat ASD or the way we conduct relevant research on ASD.
- Is **not required to have preliminary data**, but must have a sound rationale supporting the need for such a project
- Should be **considered risky** as to not likely be supported though other AS grants programs, including pilot studies.
- May come from **newer or established investigators** with demonstrated expertise and experience in autism and/or from investigators in non-autism areas of research that will be applied directly to autism research. Applicants must have a **demonstrated track record of research experience** relevant to the proposed project.

**NOTE: The relevance of the proposed research to the Autism Speaks research priority areas, described below, must be explicitly stated.**

### Research Mission

**Autism Speaks supports global biomedical research into the diagnosis, causes, prevention, and treatment of autism or its disabling symptoms.** Our mission is to improve the future for all who struggle with autism spectrum disorders. In support of that mission we provide funding along the entire research continuum -- from discovery to development to dissemination -- for innovative projects that hold considerable promise for significantly improving the lives of persons with autism.

Autism Speaks research funding will be restricted to projects that address one of the following priorities:

1. Understand **environmental risk factors** and their interaction with genetic susceptibility to enable prevention and improve diagnosis and treatment
2. Discover **biomarkers** that can improve risk assessment and subtype stratification that will allow for an individualized approach to treatment

3. Improve quality of life through **more effective medicines, behavioral interventions, and technologies**
4. Enhance diagnosis and treatment of underserved and under-studied populations, specifically,
  - **Nonverbal** persons with ASD
  - **Ethnically-diverse** and/or low resource communities
  - **Adults**
  - Those with **medical co-morbidities**
5. **Disseminate and implement evidence-based clinical practices** to the broader community worldwide

For more information on the research priority areas, please [click here](#).

### **Awards**

Autism Speaks will make a limited number of Trailblazer awards based on the quality of the submissions and available financial resources. Awards are limited to a period of 12 months and an amount up to \$100,000 total, inclusive of 10% indirect costs. Funds must be used for research expenses and cannot be used for equipment, travel, meeting, or publication costs. Training and mentoring-only applications are not appropriate for this funding program. **Project completion must be achievable within 12 months.** A one-time no cost extension (NCE) of up to 6 months may be available with a compelling justification. NCE requests are not automatically approved, and all decisions are final. NCEs may be further limited in time and amount. All unused funds must be returned at the end of the project period.

### **Post-award Procedures**

- Upon receiving notification of a potential award, the applicants must provide AS with the following documents within 30 days:
  - a. Budget breakdown and justification
  - b. Other funding sources for PIs and any paid collaborators
  - c. Evidence of sufficient subject recruitment (where appropriate)
- The grant will commence immediately upon receipt and approval of these documents and the ethical approvals outlined below, if applicable. Please note that the award will not be granted if these documents are not received by AS within 30 days of the Trailblazer Award approval notification.
- An additional 30 days (total of 60) will be allowed for Institutional approval documents, including IRB, IACUC, etc.

### **Eligibility**

Investigators holding full-time tenured or tenure-track faculty appointments or equivalent full-time non-tenure track appointments at accredited academic, medical or research institutions are eligible to apply. **Eligibility must be demonstrated at the time of registration.**

- Applicants who do not meet the eligibility criteria above (e.g., postdoctoral fellows, medical residents, clinical fellows, part-time faculty members, etc.) are eligible to apply only if the Letter of Intent section includes clear documentation from the applicant's institution stating that appointment to a full-time faculty position will be in effect by the start date of the grant.
- Applications will NOT be accepted from individuals or from proprietary organizations to support the research and development of products for profit.
- Applicants are restricted to one LOI/application per year as Principal Investigator (PI) or Co-PI.
- Overlap with other submissions to Autism Speaks or active grants from Autism Speaks should be extremely limited.

### **Investigator Qualifications**

- Applicants are required to submit NIH-style biographical sketches (four pages maximum) for themselves and any key collaborators. Publications with the greatest recency and the greatest impact should be listed. Information on history of research funding including related current, pending, and past awards should be included.

### **Application and Review Process**

Submission will be on a continuous (rolling) basis. Submission of a Letter of Intent page in the online grant system is required (see requirements below).

Autism Speaks grants and science staff will initially review each LOI for fidelity to the High Risk/High Impact purpose of the Trailblazer program and relevance to the 2010 targeted research priorities listed above. Those that are deemed exceptional in meeting the screening criteria will be invited to submit a full application.

Trailblazer applications may be submitted on a rolling basis. Applications should be no more than 5 pages in length and should include **at least** one page that clearly explains the rationale for the study. The specific aims of the application should be clearly stated along with their relevance to Autism Speaks mission and priority research areas. The specific research plan should be clearly stated. Please be reminded that successful Trailblazer applications must be able to accomplish its aims within the 12 month grant period. Applications will be reviewed quarterly by peer reviewers with expertise in autism and related research areas. After a second-level of review, the Autism Speaks' Scientific Review Panel will be responsible for funding recommendations. Autism Speaks expects to make funding decisions more rapidly for Trailblazer awards than for other types of grants. Written critiques will be made available to applicants following the review. Resubmission will require an **explicit invitation from Autism Speaks**. Such invitations will be issued sparingly. All review decisions will be final.

**\*\* 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.**

### **Submission Procedures**

**NOTE:** *Applications that do not meet submission criteria will be returned without further review.*

### **Preparing the Application**

1. **Access to the Autism Speaks Grant Administration System.** The applicant should go to <http://science.grants.autismspeaks.org> and register with your institutional email address (or log in if you have an ID). Complete your profile information.
2. **Complete a Letter of Intent.** Log in and click Applications at the top of the profile page or 'Go to Applications' at the bottom. Choose 'Start a new LOI or application', then 'Trailblazer...' from the Award Type drop down and finally "Start new letter of intent..." The Letter of Intent (LOI) includes two web pages.
  - a. **Basic Information Page includes:**
    - i. Title: Enter less than 100 characters, spaces included
    - ii. Brain Tissue Sources, as applicable
    - iii. Scientific Abstract. 2500 characters, spaces included. Provide a summary of

- the research project to be conducted. Lay Abstract. 2500 characters, spaces included. Provide a lay description of the research project. If a grant is awarded, the lay abstract may be reprinted on the Autism Speaks web site and/or in other communication materials. (2500 characters, spaces included)
- iv. **Expected Co-Investigators and collaborators** (hint: start by entering the last name). ***It is important to enter all participants you expect, even if they change later.***
  - v. All the keywords which describe this project.
  - vi. All this information will be available for editing/adding at the application stage.
- b. **Letter of Intent Form includes:**
- i. Short summary of your research topic (up to 3500 characters, spaces included)
  - ii. **The specific aims of the research must be clearly stated.**
  - iii. PI biosketch, NIH format not to exceed 4 pages
  - iv. Eligibility letter (optional) - Clear documentation for postdoctoral fellows, medical residents, clinical fellows, or part-time faculty members, etc. stating that appointment to a full-time faculty position will be in effect by the start date of the grant
3. **If your LOI is approved, you will be invited to complete the application. You will have one month from the LOI approval notification date to submit your full application.** The Responsible Official will be sent an email with grant system access instructions.
4. **Application requirements:**  
Applications are limited to the items listed below. Although no preliminary data are required, one additional figure page is allowed containing no more than two figures and their legends. No other support documents than those listed below will be accepted. All applications must be submitted online through the Autism Speaks grants administration system.
- a. **Review/edit entries on the Basic Information Page. Remaining items here are on the Application Form page.**
  - b. **Identify which Autism Speaks' target research priority is addressed by this application and explain how it is addressed. (3500 characters including spaces for explanation)**
  - c. **Describe what distinguishes the proposed research and makes it appropriate for a Trailblazer Award. (3500 characters including spaces)**
  - d. **Narrative on Rationale and Research Strategy (also refer to the Review Criteria below) – 3 pages maximum, upload file**
    - o Explain why the project is considered to be highly risky but potentially has high impact.
    - o Clearly explain the novel hypothesis or approach and methods and resources that will be used for the research.
    - o Describe the research strategy and milestones. Include information on how the research design will yield conclusive evidence of success or nonsuccess of the proposed approach.
  - e. **Investigator Qualifications** - Applicants must describe a demonstrated track record of research experience relevant to the proposed project. May come from newer or established investigators with demonstrated expertise and experience in autism

- and/or from investigators in non-autism areas of research that will be applied directly to autism research. **(3500 characters including spaces)**
- f. **References** - One page allowed, upload file
  - g. **One additional figure page** is allowed containing no more than two figures and their legends. No other support documents will be accepted.
  - h. **Biographical sketches** (four-page maximum each) for the PI and key collaborators. Key Collaborators' Biosketches must be combined into one file for upload.
  - i. **Institutional approval** – While the initial stage does not require a submitted budget, the applicant must have an institutional official approve the application. **NOTE:** Only the Responsible Official will be able to finalize the application submission.
  - j. **Letters of Collaboration** specifying the collaborator's role on the project. One page is allowed per letter.

### **Review Criteria**

***What distinguishes the proposed research and makes it appropriate for a Trailblazer Award?*** How does the research address significant roadblocks, potentially transform the field, and/or leverage exceptional opportunities? What are the high risk/high impact aspects that make the proposed project so unique or unconventional that it does not fit more traditional funding programs? Does this research represent a substantial new direction from the researchers' accomplishments to date?

***Potential Impact and Relevance to ASD:*** What is the potential impact of the research to move the field forward in unexpected, new and innovative directions? Does the project propose to overcome major impediments to advancing autism research? How could the project transform existing paradigms for understanding autism spectrum disorders and fundamentally advance our understanding of the causes, diagnosis, treatment, prevention, and/or cure of ASD? How does the proposed research align with the 2010 targeted research priorities? Is there exceptional potential for this research to have a profound impact on families, researchers, and/or service providers in the autism community?

***Research Strategy:*** What are the goals of the project? Is the project idea clearly laid out and testable? How do the proposed design, methods and analyses support these goals? Is the proposed timeline feasible for conducting high risk/high impact approach and meeting reasonable milestones? How will the proposed research design yield conclusive evidence of its potential to address roadblocks, transform the field, or leverage an exceptional opportunity (or how will it conclusively demonstrate that this is not a promising approach)?

***Researcher Qualifications:*** Do the researchers have the necessary expertise, skills and required experience to carry out the project? What is the evidence of prior innovative research efforts? Given the risky nature of the Trailblazer Award projects, do the researchers have the appropriate tools and collaborations involved identified and available in order to ensure a conclusive outcome? How will the research environment uniquely contribute to the novelty and purpose of the proposed project?

### **Grant Requirements and Deliverables**

**Recipients of Trailblazer Awards will be required to provide:**

- ***Interim Report on Progress and Projected Outcomes.*** The expected milestones or achievable goals must be submitted as part of the application to AS prior to the initiation

of the award and are subject to review by the AS science staff both at the beginning and end of the award period in order to provide individualized grant assessment criteria. Interim reports are **due at intervals of five and ten months after the start date**.

- **Final Report.** A final written report as detailed in the grant contract must be received by the Autism Speaks grant offices **within 30 days of the end of the grant**. The final report must address how the project's outcomes were met. All grant deliverables and other stipulations (i.e., requirements for public access; data and resource sharing) laid out in the standard AS grant contract shall apply to the Trailblazer Awards as well.
- **Financial Report.** A final report accounting for the monies expended must be submitted at the **end of the funding year**. Any monies not spent in accordance to the budget submitted at the beginning of the award term are cause for termination of the award and subject to restitution to Autism Speaks.

### **Other**

**Human Subjects and Vertebrate Animal 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 NOTE:** IRB, IACUC or equivalent ethical certification are NOT required at the time of applying; however, such ethical certification must be submitted as soon as possible following official notification of an award. Autism Speaks will NOT issue a grant contract or any form of funding until appropriate certifications are received.

**Projects using postmortem 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 [atportal.org](http://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. Interim reports are due at five and ten months after the start date.

### **Public Access/Dissemination:**

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. [Public Access Policy link](#)

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.

### **Contacts**

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

Joan New, MBA, Grants Associate Manager:

609-228-7313 Email: [jnew@autismspeaks.org](mailto:jnew@autismspeaks.org)

Application Development and Budgets

Anita Miller Sostek, Ph.D., Vice President, Scientific Review & Operations:  
202-384-5882; Email: [anita.sostek@autismspeaks.org](mailto:anita.sostek@autismspeaks.org)

Michael Rosanoff, MPH, Associate Director, Public Health Research & Scientific Review:  
917-475-5067; Email: [mrosanoff@autismspeaks.org](mailto:mrosanoff@autismspeaks.org)