



Request for Applications
Pilot Research
2010 Cycle

I. Introduction

Autism Speaks invites grant applications to conduct biomedical research pilot studies into the causes, diagnosis, treatment, prevention and cure of autism spectrum disorders.

Autism Speaks supports all areas of biomedical and behavioral research that will advance its research mission, including but not limited to: human brain function, language, behavior and cognition; human studies involving early detection or screening; studies on low-income, underrepresented and underserved populations; diagnosis of autism spectrum disorders (ASD) in adults; the developmental course of ASD through adolescence and aging; development of efficient and valid diagnostic instruments; behavioral, psychosocial, medical, and pharmacological treatment research; biomarkers, understanding the clinical and biological phenotypes which may potentially index autism subtype; epidemiological research; translational research; neurobiology (including anatomy, development, pathology); synaptic function and neuroplasticity; human genetics/genomics, gene discovery, genetic risk assessment; gene-environment interactions; environmental risk factors; toxicology, immunology, endocrinology; molecular and cellular physiology; studies employing model organisms including in vivo methods for defining pathophysiology; health services, comparative effectiveness studies, and dissemination sciences.

Autism pilot study applications must satisfy one or more of the following requirements:

- They employ **innovative, novel and/or untested research, diagnostic or treatment approaches and/or new biomedical or clinical paradigms**, which if successful, will likely facilitate rapid advances and/or emerging or transforming areas of research to understand the causes, diagnosis, and treatment or cure of autism spectrum disorders
- They 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
- They come from **beginning principal investigators** with demonstrated potential for and a commitment to autism research
- They come from **established investigators** with expertise and experience in other (non-autism) areas of research that are relevant and will be applied directly to autism research

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

II. Awards

Autism Speaks will make a number of pilot study awards determined by its available financial resources. Each pilot study award will be for a period one or two years in an amount not to exceed \$60,000 per year. An amount not to exceed 10% (inclusive) of the total award 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-time tenured or tenure-track faculty appointments or equivalent fulltime non-tenure track appointments at accredited academic, medical or research institutions are eligible to apply. **Eligibility must be demonstrated at the time of submitting the LOI.**

- i. Applicants who do not meet the eligibility criteria above (e.g., postdoctoral fellows, medical residents, clinical fellow, part-time faculty members, etc.) are eligible to apply only if clear documentation is provided by the applicant institution stating that appointment to a full-time, faculty position will be in effect by the start date of the grant. [will this make them try to delay start date? Do we need to put a limit?]
- ii. Although the documentation can be submitted with the full application, information pertaining to eligibility must be provided in the LOI.
- iii. Applications will NOT be accepted from individuals or from proprietary organizations to support the research and development of products for profit.
- iv. Applicants are restricted to one LOI/proposal per review cycle as Principal Investigator (PI) or Co-PI.

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 (LOIs) and Proposals must be submitted electronically in order to be accepted for review and considered for funding. LOIs and Proposals submitted in any other manner (e.g., by regular mail or by email) will not be considered. The applicant will receive confirmation of a successful electronic submission via system-generated email.

b. Investigators new to the Autism Speaks submission process:

- i. 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.
- ii. Each new applicant/investigator must first register with the grants system at 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 April 22, 2009. Proposals are due no later than June 24, 2009. All deadlines are at 11:59 PM (EST).**

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. In addition, LOIs may be reviewed for scientific merit and fidelity to the intent of the current RFA.

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 “Pilot Study 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 Pertinent Project Information” at the bottom of the page.

Letter of Intent Guidelines:

The Letter of Intent must contain two parts.

The first part cannot exceed 2 pages, and must include the following information. The LOI should be specific enough to be screened for scientific merit and fidelity to the specific RFA:

- 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 and including the PI (excludes consultants, postdoctoral fellows, students and technicians)

The second part, one page maximum, must be a letter from the institution confirming the PIs eligibility. Please refer to section III above.

Shortly after submitting the Letter of Intent, the applicant will receive a confirmation e-mail. Applicants will be notified by email of the acceptance or denial of the LOI. 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.

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 (10 pages max). See review criteria for these sections in section IX below.

- i. **Impact and Relevance**
- ii. **Innovation**
- iii. **Research Strategy**

- iv. **Investigators' Qualifications** –briefly describe (Biosketches must be provided – see J below))
- v. **Environment** – briefly describe (greater detail should be included in H described below)

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 10 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 included for the Sponsoring Institution’s indirect (overhead) costs. The total grant cannot exceed \$60,000 per year.
 - 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 detail 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. Exhibits or 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 must now go into “Preview and Submit Proposal” to complete your submission.

VIII. Updates & Additional Materials

One update up to two pages in length will be accepted on or before August 5, 2009. This document may not redesign the application in any way. The document must be emailed to Joan New, Grants Administrator, jnew@autismspeaks.org

IX. Review Process and Evaluation Criteria

Autism Speaks is committed to efficient, fair and expert review and funding of meritorious proposals. Review of scientific merit will be provided by a group of highly accomplished researchers from the Autism Speaks Scientific Advisory Board with additional expertise, as needed, from productive investigators in the research areas of the proposals.

Proposals will be evaluated using the following criteria:

Impact and Relevance

Does the proposal address an important autism-specific problem? Does the pilot study address an important autism-specific problem? If successful, is the pilot study likely to eventually lead to new knowledge or methods that will advance the goal(s) of understanding the causes, diagnosis, and treatment or cure of autism spectrum disorders?

Innovation

Does the pilot study develop and/or use 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?

Research Strategy

Are the experimental design, methods and analyses likely to achieve the desired aim(s) of the pilot study, including the development of essential preliminary data and/or the establishment of "proof of concept" for a larger study? 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?

Investigators' Qualifications

Do the investigators have the appropriate training and experience 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 intellectual rapport? Will the proposed studies benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Is the institutional support sufficient? Has access to necessary special research equipment or facilities been appropriately documented with letters of agreement?

X. Submission, Review, & Notification Schedule (subject to change)

Letter of Intent due: April 22, 2009
Proposal due: June 24, 2009
Peer review panels: October/November 2009
Notifications: January 2010
Grant start date: February 1, 2010

XI. 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.

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.

XII. Contacts:

Please address questions about proposal submission using the web-based Grants Administration System to Joan New, Grants Administrator, 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 or 202-955-3314.