



## Autism Speaks Request for Applications

### Global Autism Public Health Initiative Autism Service Development Research in Underserved Populations

Autism Speaks' Global Autism Public Health initiative (GAPH) strives to help underserved autism communities around the world develop and implement feasible, effective, and sustainable programs for enhancing autism awareness, research, and health services. ***As part of the GAPH initiative, Autism Speaks is currently seeking research grant applications that develop and pilot test scalable, community-based, culturally-sensitive autism detection and/or early intervention programs among underserved communities in the United States and/or internationally.***

This RFA is designed to solicit research proposals that aim to (1) develop generalizable model programs of autism service delivery, (2) explore innovative ways to reach low-resource and/or under-served populations, and (3) inform practices in a broad range of such populations. It is anticipated that the outcomes of the funded research will inform effectiveness research on autism detection and intervention strategies, defined specifically as research conducted in community settings that has the potential for broad dissemination of effective detection and/or treatment practices, and influence future healthcare policy change, setting the stage for future healthcare services research among underserved populations of different cultures and/or countries.

*For more information on GAPH, please visit:*

<http://www.autismspeaks.org/science/research/initiatives/gaph.php>

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

- a. RFA Release: May 5, 2011
- b. Letter of Intent: June 14, 2011, 8:00 pm (Eastern USA)
- c. LOI Notifications: Late June 2011
- d. Application due: August 10, 2011, 8:00 pm (Eastern USA)
- e. Peer review panel: October 2011
- f. Notification: December 2011
- g. Grant start date (earliest): January 2012

#### **II. Background and Purpose**

Autism spectrum disorders (ASD) are a group of neurodevelopmental disorders characterized by deficits in social behavior and communication, and a restricted range of activities. Autism symptoms vary by person from mild to severe and in many cases include associated medical conditions. Available evidence suggests that ASD transcends

social, cultural and geographic boundaries. The Centers for Disease Control and Prevention estimate that ASD affects 1 in 110 children in the United States today. The scope of the public health challenge has prompted the American Academy of Pediatrics to recommend autism screening for all children at 18 and 24 months of age. There is compelling evidence that early behavioral intervention can result in significant gains in adaptive behavior, language, and cognitive abilities and positively impact long-term outcome. While comparable autism prevalence statistics do not exist for most countries around the world, emerging epidemiologic evidence indicate that approximately 1% of the global population is likely affected by ASD. Unfortunately, many people with ASD, both in the US and across the globe, do not have access to necessary diagnostic and treatment services.

Among underserved populations, especially in low-resource settings, a major barrier to improving the health and wellbeing of children and families touched by autism is the paucity of relevant, culturally-sensitive ASD research . Perhaps not surprisingly, much of the autism research has been conducted in high-income countries and among populations with generally greater access to autism services. Thus, very little data exist to inform best practices in the developing world as well as among underserved populations in high-income countries. Without innovative health care programs, early detection and early intervention will remain extremely limited among the poor and many ethnic minority groups. Culturally appropriate, feasible, scalable, cost-effective, and sustainable methods of service delivery are necessary but typically do not exist in these settings. While many factors contribute to stigma and failure to meet the needs of individuals and families struggling with ASD, the common factors are lack of awareness, limited research, and inadequate training.

To overcome these barriers, there is a need for innovative approaches to training and service delivery that are acceptable to communities and effective in improving outcomes. Accordingly, applicants will be required to show clear evidence that collaboration among professionals, community members, and families, and sensitivity to cultural perspectives and values will be accomplished. Proposals will need to show how partnerships with local stakeholder groups will ensure that the resulting programs are sustainable and informative to policy makers. Lastly, the RFA emphasizes creative approaches that build capacity for service delivery, and offer feasible, cost-effective, innovative community-based interventions that can be delivered with fidelity.

### **III. Key Proposal Objectives**

*Autism Speaks is seeking research applications that develop and pilot test effective, community-based, culturally sensitive, scalable, and sustainable autism health service (screening, diagnosis, and/or treatment/intervention) programs among underserved communities in the United States and/or internationally. The anticipated project outcome is not to pilot a program that will determine efficacy of a particular health service, but rather the effectiveness of delivering the health service in a community-based setting.*

The following key objectives are expected to be addressed by successful applications:

- Establishing a community-based program that builds service capacity among an underserved population(s) – specifically for detection (screening and diagnosis) and/or early intervention services – and subsequently implement and pilot test that program. ***Early intervention refers to those interventions that can be delivered at the earliest age that is practical within the community that is being studied.*** Programs should be feasible, scalable, and sustainable program in a specified community.
- Clear reasoning for selecting a particular intervention model including supporting research evidence demonstrating efficacy of the intervention strategy in other studies. Consideration of the clinical needs of any individual screened and diagnosed during the conduct of the study.
- Clear background and supporting evidence must be shown for (1) why the selected population or community is considered underserved in terms of autism services (2) how the population or community is well-suited for conducting such a project in this way, and (3) demonstration that the community is motivated to collaborate on the project.
- Applications must provide scientific details and background on sample frame, including effect (impact) estimations, variance assumptions and distribution estimates of age, gender, severity, and other relevant clinical features along with other control variables. A plan for valid, reliable and reproducible interventions is required. Control groups are encouraged but not required. Pre-post designs are anticipated.
- A program evaluation component is required to assess the effectiveness of and community satisfaction with the program.
- Collaborative relationships must be demonstrated with relevant stakeholder groups and professional organizations such as, but not limited to, parent, educator, healthcare provider, and/or government associations.
- Demonstration of potential for sustainability over time, and have the potential to be expandable and/or transferable to other communities in need.

While not required of applicants, it is anticipated that the findings will be published in the peer-review literature. All applications should include a plan to broadly disseminate study objectives and findings to both professional and lay communities.

Award recipients will be expected to collaborate with other awardees for this RFA by sharing methods, their data and exploring cross-national comparisons of their findings. Researchers will be asked to consider future collaboration with investigators from

other Autism Speaks' funded research projects and initiatives through networking meetings and/or other means (e.g., teleconference, webinar, etc.).

#### **IV. Awards**

Autism Speaks will fund a limited number of research grants determined by the available financial resources. Awards will be up to \$100,000 USD per year for up to two (2) years. Funding for year 2 will be contingent upon demonstrating adequate progress in year 1 and the availability of funds. Additionally, any funding is contingent upon receipt of the signed grant agreement and proof of IRB/IACUC/equivalent ethics approval, if applicable. Awards may be reduced if funding from other sources overlaps the research plan.

A multiple country proposal will be considered for higher funding levels, not to exceed the maximum level of \$75,000 USD per country, per year. In considering a multiple country proposal reviewers will be looking for cost efficiency.

#### **V. Eligibility**

Investigators holding doctoral-level degrees and full-time faculty appointments, professional affiliations or the equivalent at non-profit, accredited academic, research or educational institutions (including schools of medicine and allied health specialties) are eligible to apply. The Principal Investigator and/or Co-Investigator need not be physically located or have a professional affiliation based in the country where the project work will be conducted, but must demonstrate collaboration with relevant parties in the community of focus as described above. 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 review cycle. All multiple submissions will be returned.

#### **VI. Submission Requirements**

Autism Speaks utilizes a web-based application system for their grant submissions. All applications, beginning with the letter of intent, must be submitted through this system.

Please Note:

- a. Principal Investigators (applicants) must first send an email from their institutional email address to [grantadmin@autismspeaks.org](mailto:grantadmin@autismspeaks.org) indicating their interest to apply to 2011 GAPH, including name, institution, office or lab address and phone #. Access information will be returned by email. There can be only one applicant. There will be a place on the LOI page to name co-investigators and collaborators.
- b. 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.*
- c. 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.

- d. Preferred file type is PDF. If your file exceeds the upload limit, try using the Fax to File tool in the grant system.
- e. Applications received after the deadline will not be accepted unless permission has been previously granted by the Autism Speaks Grants Department 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.
- f. 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 must be authorized to approve and submit an application on behalf of the institution. Typically, they are in the Office of Sponsored Programs or the equivalent (not in the applicant's department). 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.

## **VII. Submitting the Letter of Intent**

Log in and click on Start New Application and then choose 2011 GAPH. The LOI page requires the following and must be complete:

- a. Application Title: Enter less than 100 characters, spaces included
- b. Short summary of the research topic and how it relates to the priorities as described in the GAPH RFA (up to 3000 characters)
- c. Biosketch for the PI in the NIH format not to exceed 4 pages
- d. Names, emails and institutions of Co-Investigator(s) and significant collaborators
- e. The Letter of Intent Narrative – see immediately below
- f. A letter, one page maximum on letterhead and signed, from the institution's Office of Sponsored Projects (or its equivalent) or the Head of the PI's Department, School, or Division, confirming the PIs eligibility. Please refer to section V above. A downloadable form is provided on the LOI page in the grant submission system.
- g. Name and contact information for the Responsible Official from the PI's institution
- h. Letter of Intent Narrative Guidelines:  
The LOI Narrative cannot exceed 2 pages, and must include the following information:
  - With Key Proposal Objectives in mind, a concise description of the proposed project including: specific aims, methods and expected results
  - A clear justification for the relevance and potential significance of the project to the targeted priorities of the GAPH RFA as 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.
  - Any references must be included within the two page limit.

**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.**

### **VIII. 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. 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.
- b. Layperson Abstract (up to 2500 characters, spaces included) that must be easily intelligible to a knowledgeable, but non-expert, person.
- c. Research Plan (10 pages maximum). The research plan should clearly address each of the above listed Key Proposal Objectives with consideration for the following evaluation criteria (described in further detail in section X below). \*\*
  1. **Impact\*\*** in terms of potential to meaningfully improve the lives of persons struggling with Autism Spectrum Disorders in the U.S. and/or underserved communities around the world. This includes strategy to broadly disseminate study objectives and research findings to both professional and lay communities.
  2. **Relevance** to Autism Speaks' mission and 2011 research emphasis areas (described below)
  3. **Innovation** – describe how the project is novel, ground-breaking, and has the potential to move the field(s) of screening/diagnosis, treatment, and/or dissemination research in new directions
  4. **Research Strategy**, including specific aims in response to the above described Key Proposal Objectives, which may include but are not limited to participant inclusion/exclusion criteria, recruitment strategy, methods and procedures, and statistical analyses to address specific aims
  5. **Investigators' Qualifications** –briefly describe (Biosketches must be provided – see J below)
  6. **Environment** – briefly describe research environment including demonstration of collaborative relationships and why they are appropriate (See sections H and I below)
- d. 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.
- e. Bibliography with complete literature citations including titles and all authors.

**\*\* 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.**

- f. Download and complete the **GAPH Budget Form** (the link is on the application page). This must be completed in US dollars. The budget may include:
1. 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***).
  2. Research supplies, services and related expenses
  3. Essential equipment as shown in the table. A vendor estimate is required for a single item of equipment costing more than \$5000 USD.
  4. Consultants
  5. Travel to relevant meetings. It is anticipated that grantees of this award will attend the International Meeting for Autism Research annually for networking purposes and to share research methods and findings.
  6. Publication and data analysis costs
  7. 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 \$100,000 USD per year for up to two years, totaling \$200,000 USD.
  8. Collaborations: If you are collaborating with a second site, put their total amount in "Subcontract" and include their budget justifications in the Budget Justification document. Total indirect costs for both sites cannot exceed the maximum allowed.
- g. Budget Justification (4 pages max). The budget justification should provide an explanation for all lines in the budget for all years.
- h. 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.
- i. Letters of Collaboration from relevant stakeholder groups and professional organizations as described in the Key Proposal Objectives section of the RFA, if needed.
  - j. 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.
  - k. 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.

- l. 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).
- m. 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.

#### **IX. 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 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.

#### **X. 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.***

##### **Impact and Relevance**

At Autism Speaks, our goal is to change the future for all who struggle with autism spectrum disorders by accelerating discovery of the causes, treatment, prevention, and cure of autism spectrum disorder. The degree to which the proposal directly addresses the mission of Autism Speaks is a key evaluation criterion. The proposed research must also present a feasible approach to addressing Autism Speaks 2011 Research Emphasis Area: ***Dissemination of empirically-validated screening, diagnostic and treatment***

***approaches to community settings?*** Does the study have the potential, now or in the future, to address other of the Emphasis Research Areas, available here: [http://www.autismspeaks.org/docs/sciencedocs/grants/2011\\_Research\\_Emphasis\\_Areas\\_FINAL.pdf](http://www.autismspeaks.org/docs/sciencedocs/grants/2011_Research_Emphasis_Areas_FINAL.pdf) 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 proposal develop innovative and creative ideas or methods of research, diagnosis, or treatment, and/or dissemination? Does the project propose to develop or employ novel concepts, approaches or methodologies, tools, or technologies for these areas? 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 of autism research or have not been applied in the way that is proposed?

### **Research Strategy**

Has the applicant sufficiently addressed the Key Proposal Objectives as described in the RFA? Is the project proposed well designed? Are there preliminary data available to establish feasibility and support the likelihood of further success? 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? Has the applicant demonstrated sufficient consideration of the sustainability and/or expandability of the proposed effort?

### **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, databases, 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?

## **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.

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:**

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

Joan New, MBA, Senior Grants Administrator: 609-228-7313;  
email: [jnew@autismspeaks.org](mailto:jnew@autismspeaks.org)

### **Application Development:**

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