

DEADLINES

Request for Applications (RFA) released:

November 1, 2022

Letter of Intent (LOI) due:

January 4, 2023, 8:00 p.m. ET

LOI notifications sent:

January 2023

Application due:

February 14, 2023, 8:00 p.m. ET

Letters of recommendation due:

February 7, 2023

Peer review panels:

Spring 2023

Notifications:

Summer 2023

Earliest grant start date:

Fall 2023

Autism spectrum disorder (ASD) is often associated with co-occurring conditions that can compromise physical and mental health and impact behavior, development and educational outcomes. Better understanding of these co-occurring conditions is critical to improving outcomes. However, identification and treatment of co-occurring conditions is often complicated by the core impairments that characterize ASD. Furthermore, the underlying biology of ASD can affect the manifestations of these conditions and their response to treatment.

Central auditory processing disorder (CAPD), also known as auditory processing disorder (APD), includes a range of conditions within the ear and brain that affect the way individuals process information that they hear. Research estimates that CAPD affects between 2% and 7% of children (*Chermak & Musiek 1997, Bamiou 2001*), with much higher rates among adults (*Cooper & Gates, 1991*). CAPD can occur independently or co-occur with more global dysfunction, such as attention deficit disorder and other learning disorders or development disorders, including autism (*ASHA 1996, Chermak 1999, Iliadou 2009*). These diverse differences affect a wide range of auditory processing skills, such as differences in localizing, discriminating and processing speech and non-speech stimuli, ranging from various physical properties (pitch, loudness) to perception and understanding of more complex auditory information (*ASHA 2008, O'Conner 2012*).

Much research is needed to better understand neural correlates of auditory processing and their impact on behavioral outcomes; how auditory processing changes with age; correlations between autism severity and CAPD; understanding how CAPD presents in and impacts people with autism compared to other disorders; clinical approaches for evaluating CAPD; and the potential for CAPD-targeted treatments to improve the functioning of affected individuals. Ideally, studies to address these questions will be performed in a timely, statistically robust manner and generate results that are generalizable to the broad neurodevelopmental disorder community.



The Awards

Autism Speaks, with generous support from the Royal Arch Research Assistance, anticipates funding the following three awards focused on understanding, evaluating and/or treating individuals with CAPD, particularly as it relates to ASD:

- One pilot research study, at up to U.S. \$60,000 for one year, inclusive of 10% indirect costs
- One predoctoral fellowship, at up to U.S. \$40,000/yr for two years (\$25,000 stipend + \$15,000 research allowance)
- One postdoctoral fellowship, at up to U.S. \$55,000/yr for two years (at least 50% stipend)

Note: Fellowships do not include indirect costs.

Autism Speaks generally follows the NIH Salary Cap for research awards. The specific cap for this RFA is listed in the Budget section. Final funding decisions will be based on the scientific merit and fidelity to the RFA of reviewed applications.

Key Objectives

This RFA seeks proposals for research that will elucidate the relationship of auditory processes to neurobehavioral manifestations, the potential for treatments directed at auditory processes pathology to improve neurobehavior and the best clinical approaches to the evaluation and treatment of CAPD. Proposals should advance the clinical management of CAPD and associated neurobehavioral challenges by using one of the following methods:

- Clinical assessment research
- Clinical intervention research
- Identifying pathophysiologic mechanisms that are amenable to clinical translation in the very near term

Note: Applications that include the availability of better treatments both for underlying pathology as well as co-existing conditions that decrease quality of life for those with autism will be of particular interest.

The pilot or fellowship proposals most likely to be funded under this RFA will exhibit the following qualities:

- Be based on compelling scientific rationale, derived either from preclinical or preliminary clinical research
- Address the heterogeneity of etiology and presentation, either by restricting enrollment to specific, well-justified subgroups or through a scientific plan that identifies markers of stratification
- For interventional research, include examination of the mechanisms or mediators through which neurobehavioral effects are achieved
- Include a power analysis demonstrating a likelihood of producing statistically and clinically meaningful results. This should include sufficient reserve power for exploratory analyses (if included)
- Have a proven capacity to enroll an adequately sized cohort of subjects in a timely manner



Eligibility for Pilot Award

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 for the pilot grant award.

- Applications will NOT be accepted from individuals or from proprietary organizations to support the research and development of products for profit
- As Principal Investigator or Co-Investigator, all applicants are restricted to one submission for a pilot grant. Multiple submissions will not be reviewed

Eligibility for Fellowship Awards

Predoctoral Fellows: The candidate must possess the following qualifications:

- Be an enrolled student in a program leading to a research doctorate such as a Ph.D. or Sc.D., or a combined degree such as an M.D./Ph.D., in an academic department of an accredited university or health/medical institution
- Must have two or more years remaining in their program
- Must spend at least 80% of their professional time engaged exclusively in their Autism Speaks research-related activities for the duration of the award
- Cannot simultaneously hold another fellowship award during the support period
- International applications are encouraged

Postdoctoral Fellows: The candidate must possess the following qualifications:

- Hold an M.D., Ph.D. or equivalent terminal degree
- Cannot have more than 5 years of postdoctoral experience at the commencement of the award
- Must spend at least 80% of their professional time engaged exclusively on the fellowship research activities for the duration of the award
- May not simultaneously serve in an internship or residency, hold a tenure-track faculty appointment or hold another named fellowship award during the award period

Note: Postdoctoral training in the laboratory where the applicant received their graduate degree will not be reviewed.



Mentors: Prior to application, each fellowship candidate must have identified a mentor for their fellowship. Mentors must possess the following qualifications:

- Have a Ph.D. and/or an M.D. or equivalent degree and be a scientific investigator with an academic or research institutional appointment (tenured, tenure-track or equivalent position)
- Must be affiliated with a nonprofit research institution with a research mission and administrative infrastructure.
 - Non-academic institutions must have tax-exempt status documented under Section 501(c)3 of the Internal Revenue Code, or similar classification outside the United States
- The LOI must include a letter of commitment and the application must include a recommendation from the mentor as well as a jointly completed Individualized Development Plan (IDP)
- The mentor's training experience should also be documented

Important Note: Applications are strictly limited to one predoctoral or postdoctoral fellow or mentor per LOI/application process. This applies whether the mentor is primary or not. Multiple submissions will not be reviewed.



General Instructions for Preparing LOIs and Applications

- 1. Access the Autism Speaks Science Grants System.
 - Applicants should go to http://science.grants.autismspeaks.org and register with their institutional email address (or log in if they have an ID). Complete the profile information. Applicants are welcome to connect their Autism Speaks profile with their ORCID profile during the LOI portion of the process; however, it is not required unless the LOI is accepted. Fellowship candidates please see additional instructions on page 11.
- 2. ORCID profiles Autism Speaks policy requires all applicants and mentors who progress to the full application to obtain ORCID profiles. <u>Click here for instructions</u> for linking ORCID profiles to the Autism Speaks Science Grants System.
 - Applicants will not be able to work on their full application until they have connected their ORCID profile to their Autism Speaks profile. Links in the Autism Speaks Science Grant system will make this step easy.
 - Mentors: All mentors named on the application must also connect their ORCID profile to
 their Autism Speaks profile. An application will not be reviewed until this is complete. All
 mentors named on an application will receive an email with instructions; however, the
 applicant is encouraged to follow up with each individual.
- **3.** It is advisable to review the LOI page and then the Application page in the grant system well in advance of any submission date.
- **4.** Uploaded documents for LOIs and full applications should be 11-point Arial font with 1-inch margins all around; single spacing is acceptable. NIH Biosketches can be submitted with their default margins and fonts. Please do not have headers or footers (including page numbers) in submitted documents. *Applications exceeding the specified document limits will not be reviewed.*
- 5. Preferred file type is PDF and must not be encrypted. Movie files are not acceptable.
- **6.** 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 circumstances. There are no exceptions to this rule. All decisions of Autism Speaks in response to late submissions will be final. It is the applicant's responsibility to plan around holidays or any special circumstances at their institution.
- 7. 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. LOI forms are completed and submitted by the applicant. Full applications can only be submitted by the RO.
- **8.** There are no geographic restrictions on these applications. International applicants are encouraged.

Find Pilot Application instructions on page 6. Find Fellowship instructions on page 11.



Pilot Application Instructions

Note: Applications or LOIs that do not meet submission criteria will not be approved for full application.

Submitting the Letter of Intent

Log in to the <u>Autism Speaks Science Grants System</u> 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 "Royal Arch Mason Pilot 2023" from the "Award Type" drop down menu, then finally "Start new Letter of Intent".

The LOI includes two web pages—the Basic Information Page and Letter of Intent Form. The requirements for each page are as follows:

1. Basic Information Page:

- **Title:** Enter less than 100 characters, spaces included.
- **Scientific Abstract:** 1,500 characters, spaces included. Provide a summary of the research project to be conducted.
- **Key Personnel:** Name expected co-investigators and collaborators. Hint: start by entering the last name. Many researchers are already in our database. If you need to add someone new, you must use their institutional email address. *It is important to enter all anticipated participants, even if they change later.*
- **Responsible Official (RO):** First, check the drop-down list for officials from your institution who are already in the system. If needed, add a new person using their institutional email address. The RO will be copied on the LOI confirmation email but has no responsibilities until it is time to submit the full application. The RO can view the LOI or application at any time.
- Keywords: Carefully select all the relevant keywords associated with the research project. This
 information is used to select expert reviewers who are knowledgeable about your particular field
 of study.

Note: All this information will be available for editing/adding at the application stage.

2. Letter of Intent Form:

- Letter of Intent Narrative: Two-page maximum. Should include:
 - 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 priority research area for this RFA as described in the introduction
 - Any references must be included in these two pages
 - The LOI should be specific enough to be screened for scientific merit and fidelity to the purpose of this RFA
- Principal Investigator Biosketch: NIH format, not to exceed five pages. More recent publications
 and those with greater relevance to the grant submission should be listed. Information on history of
 research funding including related current, pending and past awards should be included.



- **Biosketches for Co-investigators and Significant Research Collaborators:** NIH format, not to exceed five pages per person. Combine biosketches into one file for upload.
- **Eligibility Letter (optional):** Clear documentation for postdoctoral fellows, medical residents, clinical fellows, 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.

Important Note: The applicant will receive a notification email after Autism Speaks staff reviews the submitted LOI. Applicants with approved LOIs will be invited to move to the full application.

Submitting the Full Application

Note: Autism Speaks policy requires all applicants and mentors to obtain ORCID profiles. <u>Click here for instructions</u> for linking ORCID profiles to the Autism Speaks Science Grants System. <u>See General Instructions</u> for preparing LOIs and applications on page 5.

SUBMIT A FULL APPLICATION WITH THE INFORMATION OUTLINED BELOW

Applicants are limited to these items; no other supporting documents will be accepted.

- 1. Review/edit entries on the **Basic Information Page**. The remaining items below are found on the **Application Form Page**.
- **2. Research Narrative:** Six-page maximum. The research plan should address the evaluation criteria below:
 - Impact explain the potential of the project to improve the lives of persons struggling with CAPD
 - Innovation describe how the project is novel and has the potential to move the field forward
 - Research Strategy describe the specific aims, participant exclusion/inclusion criteria, recruitment strategy, methods and procedures and statistical analyses, including power analyses, to address specific aims
- **3. Figures:** Include a maximum of two pages of relevant images, figures and graphics. Images uploaded here will not be counted towards the six-page limit.
- **4. References:** Include complete literature citations, including titles and all authors. References are not included in the six-page limit.
- 5. Budget Table: Complete the online budget table (in U.S. Dollars). The budget may include:
 - *Personnel costs* (not to exceed the percent effort committed to the proposed project). The full-time employee salary cap is U.S. \$204,000
 - Principal investigator and/or co-investigator salaries and benefits
 - Technical research assistant salary and benefits
 - Research assistant or fellow stipends and benefits are allowed
 Note: Tuition reimbursement is not allowed



- Research supplies, services and related expenses
- *Essential equipment.* A vendor estimate is required for a single item of equipment costing more than U.S. \$5,000
- Consultants
- Travel to professional meetings
- Publication and data analysis costs
- *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 U.S. \$60,000
- Collaborations: If you are collaborating with a second site, put their total direct amount in a
 "subcontract" row and include an appropriate explanation in the budget justification section.
 Total indirect costs for both sites cannot exceed the maximum allowed.
- **6. Budget Justification:** Four-page maximum. Provide an explanation for all lines in the budget. Include explanations for subcontract budgets as appropriate.
- 7. Human Participants and/or Vertebrate Animals: Applications that use human participants or vertebrate animals must address issues of protections. If no ethics approval is needed for the proposed research, please upload a memo to that effect. Note that ethical approvals from the applicant organization are required before an award will be made. These approvals do not serve in lieu of the information requested below.
 - *Human participants* (defined as living individuals)
 - Scientifically justify the involvement of human participants in the proposed research.
 - Describe in detail the plan for the involvement of human participants in the proposed research.
 - Vertebrate animals
 - Describe in detail the proposed use of the animals, including species, strains, ages, sex and number to be used.
 - Justify the use of animals, choice of species and numbers to be used.
 - Provide information on the veterinary care of the animals.
 - Describe procedures for ensuring discomfort, distress, pain and injury is minimized. Please include the method of euthanasia and the reasons for its selection.
- **8. Consent Form and Consent Procedures:** Please attach any consent forms that are to be used in the study, along with a summary of the procedures surrounding how consent will be obtained. Make a note if the forms have not yet been approved.
- **9. Resources and Research Environment:** One-page maximum. Describe the resources and environment that will support the successful completion of the project. If the project will use existing samples and/or collecting samples, specify how and when they will be used and shared with the autism community following the end of the project.



- 10. Letters of Collaboration: We require appropriate letters of collaboration and support to demonstrate sustainability and partnership. These letters should also outline what the collaborators are willing to contribute in time, effort, resources and infrastructure. All those whose salary, in whole or in part, will be covered by the grant should be included in the budget. Combine multiple letters into one file for upload. In general, consultants should provide letters but paid co-investigators are not required.
- 11. Biographical Sketches (Biosketches): Upload biosketches for the principal investigator, named co-investigators and collaborators in NIH format. Five-page maximum each. Indicate education and complete citations (including title) of publications *relevant to the proposed research*, and briefly describe current and pending grant support. While not required, biosketches for consultants are recommended. There is one upload slot for the PI biosketch. Other biosketches must be combined into one file for upload.
- **12. Supporting Files:** Other documents 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.
- **13. Peer-reviewed Research Publications:** A maximum of two (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.**

SUBMIT THE APPLICATION FOR INSTITUTIONAL APPROVAL

When the applicant is ready, they should click the "Ready for RO" link at the bottom of the application form page. The system will send an email to the Responsible Official who will then be able to review and submit the application. The RO can view the application at any time. The RO can also revert the application to draft if changes are needed. After making such changes, the applicant should click "Ready for RO" again.



Other Information

Post Award

The recipient of any grant from Autism Speaks must use the awarded funds as specified in the approved budget. Any funds not used in the above specified manner must be returned to Autism Speaks. Payment of the awards is contingent on receiving any institutional approvals (IRB or IACUC) that may be required for the research.

Review Process and Evaluation Criteria

Applications will be reviewed by independent peer review panels that will include active and experienced investigators in the research areas of the applications as well as our partners in the broader CAPD community. Fellowship applications will be reviewed on the merit of the training plan, the proposed research, the strength of the candidate and mentor, and the relevance to advancing the mission of Autism Speaks, which is to advance research into causes and better interventions for autism spectrum disorder and related conditions.

Miscellaneous

Human subjects and vertebrate animal certifications must be documented with a copy of an official letter of approval (or equivalent for non-U.S. applicants) identifying the principal investigator, project title as submitted to Autism Speaks and date of approval. It must be 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.

Contacts

Grants Administration/Online Application/Budget Questions:

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

Application Development:

Donna Murray, Ph.D., Vice President of Clinical Programs: donna.murray@autismspeaks.org



Fellowship Instructions

Autism Speaks limits the application procedure to only one fellowship submission from any fellow or mentor per year. This applies to the Letter of Intent as well as the full application. However, a mentor may be named for both one predoctoral and one postdoctoral applicant.

General Information

- 1. All applications must be submitted through the Autism Speaks Science Grants System at https://science.grants.autismspeaks.org. See general instructions for preparing letters of intent and full applications on page 5.
- **2. The fellowship candidate must be the applicant.** If you are new to the Autism Speaks Science Grants system, register with your *institutional email address*. Otherwise, log in to your previously established account. We recommend using the following browsers: Chrome, Firefox, Safari or Edge (Mobile browsers and tablet-based browsers are not currently supported.) Complete your profile information.
 - *Note:* Applicants should list their primary institution as the location where their proposed research will occur. This is especially important if the fellow is moving to a new institution for their doctoral program.
- **3. Fellows should use the regular NIH biosketch** rather than the fellow biosketch.

Submitting the Letter of Intent

Log in and click "Applications" at the top of the profile page or "Go to Applications" at the bottom of the page. Choose "Start a new LOI or application".

Predoctoral applicants choose "Royal Arch Masons Predoctoral Fellowship 2023" **Postdoctoral applicants** choose "Royal Arch Masons Postdoctoral Fellowship 2023"

The LOI includes two web pages—the Basic Information Page and the Letter of Intent Form. The requirements for each page are as follows:

- 1. Basic Information Page:
 - **Title:** Enter less than 100 characters, spaces included
 - Scientific abstract: 1,500 characters, spaces included. Describe the project goal(s) and/or hypothesis, specific aims, research methods, expected results and significance/relevance to CAPD research areas as stated above.
 - **Key personnel: Mentors and consultants:** Enter all individuals participating in the research project. Hint: start by entering the last name. Many researchers are already in our database. If you need to add someone new, you must use their institutional email address. Final changes to this list can be made during completion of the application.



- **Responsible Official (RO):** Choose the RO from the Pl's institution. First, check the drop-down list for officials from your institution who are already in the system. If needed, add a new person using their institutional email address. A mentor cannot also serve as an RO.
- **Keywords:** Carefully select all the relevant keywords associated with the research project. This information is used to select expert reviewers who are knowledgeable about your particular field of study.

Note: All this information will be available for review and editing during the application stage.

2. Letter of Intent Form:

- Graduation/Experience:
 - *Predoctoral applicants:* Enter your expected graduation date. Note: It is understood it is an estimate, but applicants should have two full years remaining.
 - *Postdoctoral applicants:* Enter the year of your Ph.D./M.D. Applicants should not have more than five years of postdoctoral experience at the commencement of the award.
- **Training Plan Summary:** 4,000 characters, spaces included. Short summary of the training plan and how it will contribute to the fellow's career development, including training activities outside of the research (courses, rotations, conferences, etc.).
- **Fellow Biosketch:** NIH format, not to exceed five pages. Biosketches should only contain published or in-press manuscripts.
- Primary Mentor Biosketch: NIH format, not to exceed five pages.
- Other Mentor Biosketches (if applicable): NIH format, not to exceed five pages per person.
- Statement of Commitment from the Primary Mentor: Describe the availability of resources essential to achieve the specific aims and career goals of the fellow. Include the mentor's training experience. This should NOT be a letter of recommendation for the fellow.

Note: The applicant will receive a notification email after Autism Speaks staff reviews the submitted LOI. Applicants with approved LOIs will be invited to move to the full application.



Submitting the Full Application

Note: Autism Speaks policy requires all applicants and mentors to obtain ORCID profiles. <u>Click</u> <u>here for instructions</u> for linking ORCID profiles to the Autism Speaks Science Grants System. <u>See</u> General Instructions for preparing LOIs and applications on page 5.

SUBMIT A FULL APPLICATION WITH THE INFORMATION OUTLINED BELOW

Applicants are limited to these items; no other supporting documents will be accepted.

- 1. Review/edit entries on the Basic Information Page. This is the same page that was completed for the LOI (see instructions on page 5). Additionally, there will be a section for Recommendations (see #16 below).
- 2. The remaining items below are found on the Application Form Page.
- **3. Research plan:** Six-page maximum, uploaded document. Include:
 - **a.** Specific aims, background and significance/relevance to CAPD.
 - **b.** Preliminary data, including images or figures if applicable. Note that any relevant publications, high resolution photographs or other supporting material can be uploaded under Exhibits.
 - **c.** Experimental design and methodology for achievement of specific aims.
- **4. Timeline:** Create a timeline showing the expected milestones for the achievement of the aims.
- 5. Individualized Development Plan (IDP): Three-page maximum, uploaded document. The Royal Arch Mason Fellowship program is dedicated to encouraging promising scientists to join the CAPD research community as productive researchers. The mentor's role is to foster the development of the fellow's overall knowledge of CAPD and assist the fellow in meeting their career goals. Therefore, the IDP must include a description of the research and educational environment, and a statement of commitment to provide resources essential to achieve the specific aims and career goals of the fellow. The mentor must provide a tailored IDP for the applicant. The plan must list experiences that are specific and individualized and that build on the fellow's previous experiences while expanding their knowledge and experience in CAPD. These may include coursework, workshops, seminars and collaborative interactions with other researchers within and outside the field of primary study, in relation to the applicant's research career goals. The training should add value above and beyond previous educational and research experiences. Describe the research training environment and available resources (facilities, equipment, study populations and intellectual activities). The applicant must also relate the expected value of the proposed fellowship experience and research training program to their needs in preparation for a career as an independent researcher in the area of CAPD.

Note: All mentors should sign the IDP.



- **6. Responsible Conduct of Research Plan:** Three-page maximum, uploaded document. Outline all previous, current and future instruction on the responsible conduct of research. These plans may include coursework as well as individual and/or group training sessions with faculty and should detail the duration and frequency of instruction. The mentor's role in promoting and ensuring the responsible conduct of research must be described. Please note, participating in online courses alone will not be considered sufficient instruction in the responsible conduct of research. In addition, while training in professional ethics, ethics in clinical research or the ethical use of vertebrate animals is commendable and recommended, these topics are not sufficient to cover all aspects of responsible research conduct. See Appendix on page 18 for a list of topics.
- **7. Bibliography:** Include complete literature citations including titles and all authors. Uploaded document.

8. Budget:

- **a. Predoctoral applicants** must complete the online budget table showing how the U.S. \$15,000 research allowance will be spent. Allowable categories are tuition reimbursement, fringe benefits, research supplies, travel, animal/human subjects costs and others (must be explained in the Budget Justification). Indirect costs are not allowed. The stipend will be included automatically and cannot be changed or reallocated.
- **b. Postdoctoral applicants** must enter the number of years' experience at the top of the budget table. The table will then show a \$27,500 stipend (50% of the award). The remaining \$27,500 can be allocated among these allowable categories: additional stipend, tuition reimbursement, fringe benefits, research supplies, travel, animal/human subjects' costs and others (must be explained in the Budget Justification). Indirect costs are not allowed.
- **9. Budget Justification:** Provide a detailed justification for each item on the budget. Include calculation(s) used. Uploaded document.
- 10. Human Subjects and/or Vertebrate Animals: 5,000 character maximum, spaces included. Applications that use human subjects or vertebrate animals must address issues of protections, including the applicable issues listed below. Please state if no human or vertebrate animals will be used in the project. Note that ethical approvals from the applicant organization are required before an award will be made. These approvals do not serve in lieu of the information requested below.
 - *Human participants* (defined as living individuals)
 - Scientifically justify the involvement of human subjects in the proposed research.
 - Describe in detail the plan for the involvement of human subjects in the proposed research.
 - Describe in detail the potential risks to participants and measures to be taken to protect human subjects from those research risks.
 - For clinical trials, describe plans for data and safety monitoring, including the description of a data and safety monitoring board if necessary.
 - If the project proposes no involvement of human subjects but uses existing human data or biological specimens, justify the claim of non-involvement of human subjects.



• Vertebrate animals

- Describe in detail the proposed use of the animals, including species, strains, ages, sex and number to be used.
- Justify the use of animals, choice of species and numbers to be used.
- Provide information on the veterinary care of the animals.
- Describe procedures for ensuring that discomfort, distress, pain and injury are minimized. Please include the method of euthanasia and the reasons for its selection.
- **11. Consent Forms (if applicable):** If this project will involve human subjects, upload the consent forms that will be used with the participants. Please note if they have not yet been approved by IRB.
- **12. Letters of Collaboration (optional):** Up to two one-page letters of collaboration may be submitted describing a collaborative arrangement. Combine multiple letters for upload.
- 13. Biographical Sketches (Biosketches): Upload biosketches for all key personnel in NIH format. Five-page maximum each. There are individual upload slots for the fellow and primary mentor. All other biosketches should be combined into one document for upload, organized in alphabetical order by last name. Consultant biosketches are not required but strongly suggested. Biosketches should indicate all active and recently completed public and private funding, including source, total award amount, award duration (inclusive dates) and project title, for both the applicant and the primary mentor. Clearly explain the extent to which currently funded research projects will overlap, complement and/or contribute to the proposed research. Uploaded document.
- **14. Publications:** A maximum of two publications that support the project can be uploaded. These do not have to be authored by the fellow or the mentor. **Publication files MUST NOT be locked or secured in any way.**
- **15. Exhibits:** Supplemental exhibits that support the Research Plan can be submitted. Multiple items should be combined into one file. Items uploaded in this section will be reviewed at the discretion of the reviewer.
- 16. Recommendations: A minimum of three confidential recommendations must be submitted by the primary mentor, other named mentors and at least one non-mentor referee. The typical applicant will have recommendations from a primary mentor and two referees. Instructions for applicants and responsible officials can be downloaded <u>HERE</u>. Instructions for mentors and referees can be downloaded <u>HERE</u>. The recommendations must be completed in the Autism Speaks Science Grants System (no uploads) and will address the following information about the candidate:
 - Commitment to a career focusing on CAPD-oriented research
 - Potential for conducting research
 - Adequacy of scientific and academic background, with specific reference to the candidate's academic and research endeavors, including any publications to date
 - Evidence of originality



- Specific areas of further research training that would benefit the candidate
- Any additional related comments that the referee may wish to provide

Important Note: It is the responsibility of the fellow to make sure each mentor and referee have the above instructions. These submissions must be received on or before the deadline listed on page 1.

SUBMIT THE APPLICATION FOR INSTITUTIONAL APPROVAL.

When the application is complete, the applicant will click "Ready for RO Approval" on the Application Form page.

This can be done without all the recommendation letters submitted; however, the Responsible Official will not be able to submit the application unless all letters are submitted.

It is the responsibility of the applicant to contact their Responsible Official who must complete the submission. Applications must be submitted electronically using the Autism Speaks Science Grants System. Applications that are late, incomplete, exceed the document limitations, or do not adhere to the required format will not be reviewed. Neither will faxed or emailed applications be reviewed.

Autism Speaks reserves the right to return without review any fellowship application that in its judgment is not:

- Compliant with its rules and procedures for application preparation and submission
- Responsive to its research training goals
- 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.

Other Information

Notifications and Announcements

Applicants will be notified by e-mail after the funding decision process is complete. All grant awards shall be posted on the Autism Speaks website.

Post Award

The recipient of any grant from Autism Speaks must use the awarded funds as specified in the approved budget. Any funds not used in the above specified manner must be returned to Autism Speaks. Payment of the awards is contingent on receiving any institutional approvals (IRB or IACUC) that may be required for the research.

Fellowships payments will be contingent upon completion and submission of the appropriate documents, as explained in the grant agreement. A fellowship award cannot be transferred to another mentor, laboratory or sponsoring institution without prior written approval from Autism Speaks. Fellowships cannot be transferred to another fellow.



Fellows will be required to provide a public seminar about their work during the life of the grant. Additionally, at the conclusion of the grant, fellows will be required to write a summary of their findings, appropriate for the lay community, which may be posted on the Autism Speaks website. Autism Speaks science staff will work with the fellow on these requirements.

Review Process and Evaluation Criteria

Applications will be reviewed by independent peer-review panels that will include active and experienced investigators in the research areas of the applications as well as our partners in the broader CAPD community. Fellowship applications will be reviewed on the merit of the training plan, the proposed research, the strength of the candidate and mentor, and the relevance to advancing the mission of Autism Speaks, which is to advance research into causes and better interventions for autism spectrum disorder and related conditions.

Miscellaneous

Human subjects and vertebrate animal certifications must be documented with a copy of an official letter of approval (or equivalent for non-U.S. applicants) that 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 to submit an application;* however, such ethical certification must be submitted as soon as possible following official notification of an award. Autism Speaks will NOT issue any 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. Use the Exhibits slot to upload the documentation and mention it in the Research Plan. (Note: If there are other documents to be included in the Exhibits upload, they will have to be combined into one document for upload.)

Contacts

Grants Administration/Online Application/Budget Questions:

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

Application Development:

Donna Murray, Ph.D., Vice President of Clinical Programs: donna.murray@autismspeaks.org



APPENDIX:

Responsible Conduct of Research Plan for Fellowship Applicants

Outline all previous, current and future instruction on the responsible conduct of research. These plans may include coursework as well as individual and/or group training sessions with faculty and should detail the duration and frequency of instruction. The mentor's role in promoting and ensuring the responsible conduct of research must be described.

Please note, participating in online courses alone will not be considered sufficient instruction in the responsible conduct of research. In addition, while training in professional ethics, ethics in clinical research or the ethical use of vertebrate animals is commendable and recommended, these topics are not sufficient to cover all aspects of responsible research conduct.

Responsible conduct of research includes most of the professional activities that are related to a research career and specifically encompasses the following nine areas:

- 1. Conflict of interest personal, professional and financial
- **2.** Policies regarding human subjects, live vertebrate animal subjects in research and safe laboratory practices
- 3. Sponsor/fellow responsibilities and relationships
- 4. Collaborative research, including collaborations with industry
- **5.** Peer review, including confidentiality and disclosure of participation by anyone not directly assigned to the materials under review
- 6. Data acquisition and laboratory tools; data management, sharing and ownership
- 7. Research misconduct and policies for handling misconduct
- **8.** Responsible authorship and publication, with topics including fabrication, falsification and plagiarism
- **9.** The scientist as a responsible member of society, contemporary ethical issues in biomedical research and the environmental and societal impacts of scientific research

Document requirements: Word or PDF, three-page maximum, Arial 11-point font, 1-inch margins, single spaced is acceptable.

