



Autism Speaks Research on Central Auditory Processing Disorders Request for Applications Pilot Grant and Fellowship Funding

**Research made possible by generous support
from the General Grand Chapter of the Royal Arch Masons International**

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

RFA released: November 8, 2021
Letter of Intent due: December 14, 2021, 8:00 PM Eastern
LOI notifications sent: Late December 2021/Early January 2022
Application due: February 16, 2022, 8:00 PM Eastern
Recommendations for Fellowships due February 9, 2022

Peer review panels: Spring 2022
Notifications: Early Summer 2022
Earliest Grant start date: Late Summer/Fall 2022

Overview

Autism Speaks, with generous support from the Royal Arch Research Assistance, anticipates funding one pilot research award, at up to US \$60,000 (one year), one predoctoral fellowship award, at up to US \$40,000/yr (two years), and one postdoctoral award, at up to US \$55,000/yr (two years) focused on understanding, evaluating and/or treating individuals with central auditory processing disorder (CAPD), particularly as it relates to autism spectrum disorder (ASD). Final funding decisions will be based on the scientific merit and fidelity to the RFA of reviewed applications.

Introduction

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.

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 percent and 7 percent 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 and 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 as compared to 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.

Key Objectives

This request for applications (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, either by clinical assessment research, clinical intervention research or by identifying pathophysiologic mechanisms that are amenable to clinical translation in the very near term. 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.

Awards

Autism Speaks will make awards based on the quality of the submissions and available financial resources. Pilot grant awards are limited to one year and an amount up to \$60,000 US, inclusive of 10 percent 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.

Predocutorial fellowship awards are limited to two years and an amount of \$40,000 US per year for two years (\$25,000 US stipend + \$15,000 US research allowance). Postdoctoral fellowship awards are limited to \$55,000 US per year for two years (at least 50% Stipend). Fellowships do not include indirect costs.

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 per process. *Multiple submissions will not be reviewed.*

Eligibility for Fellowship Awards

Predoctoral Fellows: The candidate must 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. The candidate must have two or more years remaining in the program. The selected predoctoral fellow must spend at least 60 percent of his/her professional time engaged exclusively in their Autism Speaks research-related activities for the duration of the award, and cannot simultaneously hold another fellowship award during the support period. International applications are encouraged.

Postdoctoral Fellows:

The candidate must hold an M.D., Ph.D. or equivalent terminal degree and cannot have more than 5 years of postdoctoral experience at the commencement of the award. The selected postdoctoral fellow must spend at least 80 percent of his/her professional time engaged exclusively on the fellowship research activities for the duration of the award. The fellow 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. Postdoctoral training in the laboratory where the applicant received his/her graduate degree will not be reviewed.

Mentors for both fellowships: Prior to application, each fellowship applicant must have identified a mentor for his/her fellowship. Mentors must 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). The mentor 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 letter of intent (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. The mentor's training experience should also be documented. The mentor's role is to foster the development of the fellow's overall knowledge of CAPD and assist the fellow in meeting his/her career goals.

Applications are strictly limited to one per pre/postdoctoral fellow or mentor per LOI/application process. This applies whether the mentor is primary or not. Multiple submissions will be returned.

General Instructions for preparing letters of intent and applications

1. **Access to the Autism Speaks Science Grants 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. 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 9.**
2. **ORCID profiles** – Autism Speaks policy requires all applicants and mentors to obtain ORCID profiles. [Link to Help document.](#)
 - a. **Applicants** will not be able to work on their 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.
 - b. **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 circumstance. 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.

Pilot award instructions – page 5

Fellowship award instructions - page 9

Pilot Application Instructions

NOTE: Applications or Letters of Intent that do not meet submission criteria will be returned without further review.

1. **Complete a Letter of Intent.** Log in to <http://science.grants.autismspeaks.org> 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 2022” 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. Scientific Abstract. 1,500 characters, spaces included. Provide a summary of the research project to be conducted.
- iii. Enter Key Personnel: Name expected co-investigators and collaborators. Many researchers are in our database (Hint: Start by entering the last name.). 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.***
- iv. Name the Responsible Official (RO). First check the drop-down list for officials from your institution already in the system. If needed, add a new person using their institutional email address. The RO will be copied on the confirmation email but has no responsibilities until it is time to submit the application. The RO can view the LOI or application at any time.
- v. Choose the keywords that describe this project.
- vi. All this information will be available for editing/adding at the application stage.

b. Letter of Intent Form includes:

- i. Letter of Intent Narrative: Two-page maximum. Should include:
 1. A concise description of the proposed project including: specific aims, methods and expected results
 2. A clear justification for the relevance and potential significance of the project to the priority research area for this RFA described in the introduction
 3. Any references must be included in the two pages.
 4. The LOI should be specific enough to be screened for scientific merit and fidelity to the purpose of this RFA.
- ii. PI 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.
- iii. Biosketches for co-investigators and research collaborators, NIH format not to exceed five pages per person. While not required, biosketches for consultants are recommended. Combine biosketches into one file for upload.
- 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.

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

2. Preparing the Application

- a. **ORCID profiles** – Autism Speaks policy requires all applicants and mentors to obtain ORCID profiles. [Link to Help document](#). See General Instructions for details (pg 3).
- b. **Application requirements/procedures:** Applications are limited to the items listed below; no other supporting documents will be accepted.
 - i. **Review/edit entries on the Basic Information Page.** Remaining items here are on the Application Form page.
 - ii. **Research Narrative:** (six pages maximum) The research plan should address the evaluation criteria below:
 - a) **Impact** in terms of potential to improve the lives of persons struggling with CAPD
 - b) **Innovation** – describe how the project is novel and has the potential to move the field forward
 - c) **Research Strategy**, including specific aims, participant exclusion/inclusion criteria, recruitment strategy, methods and procedures, and statistical analyses, including power analyses, to address specific aims
 - iii. **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.
 - iv. **References:** Include complete literature citations including titles and all authors. References are not included in the six-page limit.
 - v. **Budget Table:** Complete the online budget table (in USD). The budget may include:
 - a) Personnel Costs (not to exceed the percent effort committed to the proposed project) FTE Salary cap is \$200,000 US.
 - 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**).
 - Consultants
 - b) Research supplies, services, and related expenses
 - c) Essential equipment. A vendor estimate is required for a single item of equipment costing more than \$5000 US.
 - d) Travel to professional meetings
 - e) Publication and data analysis costs
 - f) Animal/Human Subjects Costs
 - g) Indirect costs: An amount not to exceed 10 percent of direct costs may be included for the sponsoring institution's indirect (overhead) costs. The total grant cannot exceed \$60,000 US.
 - h) 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. Indirects will be automatically calculated.
 - vi. **Budget justification** (four pages maximum) Provide an explanation for all lines in the budget. Include explanations for subcontract budgets as appropriate.
 - vii. **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.

a) 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.
- Describe in detail the potential risks to participants and measures to be taken to protect participants 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.

b) 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.

- viii. **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.
- ix. **Resources and research environment:** (one-page max) 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.
- x. **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.
- xi. **Biographical sketches:** For the principal investigator, named co-investigators and collaborators in NIH format (five pages 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.
- xii. **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.
- xiii. **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.

3. **Submission/institutional approval** –When the applicant is ready, he/she 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 (RO) 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. The applicant should contact the RO directly whenever the application is ready for review to ensure the RO is aware.

Other Information

Human subjects and vertebrate animal certifications must be documented with a copy of an official letter of approval (or equivalent for non-US 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.

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.

Contacts

Grants Administration/Online Application/Budget Questions:

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

Application Development:

Donna Murray PhD, Vice President, Clinical Programs: donna.murray@autismspeaks.org

Fellowship Instructions

Autism Speaks limits the application procedure to only one fellowship submission from any fellow per process and applies to the Letter of Intent (LOI) as well as the full application. Any mentor may be named on only one LOI/application per process. However, a mentor may be named for both one predoctoral and one postdoctoral applicant.

General Information (also see General Information on page 3)

All applications must be submitted through the web-based Autism Speaks Science Grants System - <https://science.grants.autismspeaks.org>.

Please Note:

1. 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 IE 10 and higher (Mobile browsers and tablet-based browsers are not currently supported.) Complete your profile information. *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.*
2. Fellows should use the regular NIH biosketch rather than the fellow biosketch.

Submitting the Letter of Intent (LOI)

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” then

Predoctoral applicants choose “Royal Arch Masons Predoctoral Fellowship 2022”

Postdoctoral applicants choose “Royal Arch Masons Postdoctoral Fellowship 2022”

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

1. Basic Information Page includes:
 - a. **Title:** Enter less than 100 characters, spaces included
 - b. **Scientific abstract:** Describe the project goal(s) and/or hypothesis, specific aims, research methods, expected results and significance/relevance to CAPD research areas as stated above. (up to 1,500 characters, spaces included)
 - c. **Key personnel: Mentors and consultants** (Tip: Start by entering the last name.) It is important to enter all individuals participating in the research project. Final changes to this list can be made during completion of the application.
 - d. **Responsible official:** Choose the Responsible Official (RO) from the PI’s institution. You must have an institutional email to add a new person. *A mentor cannot also serve as an RO.*
 - e. **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.
 - f. **Note:** All this information will be available for review and editing during the application stage.
2. Letter of Intent Form includes:
 - a. **Graduation/Experience:**
 - i. **Predoctoral applicants:** Enter your expected graduation date. It is understood it is an estimate, but applicants should have two full years remaining.

- ii. **Postdoctoral applicants:** Enter the year of your PhD/MD. Applicants should not have more than 5 years of postdoctoral experience at the commencement of the award.
- b. **Training plan summary:** 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.). (up to 4,000 characters, spaces included)
- c. **Fellow biosketch:** NIH format not to exceed five pages. Biosketches should only contain published or in-press manuscripts.
- d. **Primary mentor biosketch:** NIH format not to exceed five pages
- e. **Other mentor biosketches, if applicable:** NIH format not to exceed five pages per person
- f. **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.

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

Complete the full application.

1. **ORCID profiles –** Autism Speaks policy requires all applicants and mentors to obtain ORCID profiles. [Link to help document](#). See also *General Information on page 3*.
2. **Basic information page:** This is the same as for the LOI (See list above). Review and edit the entries. Additionally, there will be a section for Recommendations. See information in #18 below.
3. ***All the remaining items will be found on the Application Form page.***
4. **Research plan.** Not to exceed six pages, 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.
5. **Timeline:** Create a timeline showing the expected milestones for the achievement of the aims.
6. **Individualized Development Plan (IDP).** Not to exceed three pages, uploaded document. The Royal Arch Mason Fellowship program is dedicated to encouraging promising scientists to join the Central Auditory Processing (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 his/her 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 his or her 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 his or her needs in preparation for a career as an independent researcher in the area of CAPD. **All mentors should sign the IDP.**

7. **Responsible conduct of research plan:** Not to exceed three pages, uploaded document. Outline all previous, current and future instruction. 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 for list of topics.
8. **Bibliography** with complete literature citations including titles and all authors. Uploaded document.
9. **Budget.**
 - a. **Predoctoral applicants** must complete the online budget table showing how the \$15,000 US research allowance will be spent. Allowable categories are tuition reimbursement, fringe benefits, research supplies, travel, animal/human subjects' costs and other (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 # 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: stipend (addl.), tuition reimbursement, fringe benefits, research supplies, travel, animal/human subjects' costs and other (must be explained in the budget justification). Indirect costs are not allowed.
10. **Budget justification.** Provide a detailed justification for each item on the budget. Include calculation(s) used. Uploaded document.
11. **Inclusion of human subjects and/or vertebrate animals:** Applications that use human subjects or vertebrate animals must address issues of protections, including the applicable issues listed below. (up to 5,000 characters, spaces included) *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.*
 - a. **HUMAN SUBJECTS** (defined as living individuals)
 - i. Scientifically justify the involvement of human subjects in the proposed research.
 - ii. Describe in detail the plan for the involvement of human subjects in the proposed research.
 - iii. Describe in detail the potential risks to participants and measures to be taken to protect human subjects from those research risks.
 - iv. For clinical trials, describe plans for data and safety monitoring, including the description of a data and safety monitoring board if necessary.
 - v. 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.

b. VERTEBRATE ANIMALS

- i. Describe in detail the proposed use of the animals, including species, strains, ages, sex and number to be used.
- ii. Justify the use of animals, choice of species and numbers to be used
- iii. Provide information on the veterinary care of the animals.
- iv. Describe procedures for ensuring that discomfort, distress, pain and injury are minimized. Please include the method of euthanasia and the reasons for its selection.

c. Please state if no human or vertebrate animals will be used in the project.

12. **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.
13. **Letters of collaboration** (optional): Up to two one-page letters of collaboration may be submitted describing a collaborative arrangement. Combine multiple letters for upload.
14. **Biographical sketches**: Include all key personnel, not to exceed five pages per individual. Please use the NIH Biographical Sketch format. There are individual upload slots for the fellow and primary mentor. All other bios 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.
15. **Publications**: Upload up to two publications that support the project can be uploaded. These do not have to be authored by the fellow or the mentor. The files **MUST NOT** be locked or secured in any way.
16. **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.
17. **Three confidential recommendations (minimum)**: Must be submitted in the Autism Speaks Science Grants System by the primary mentor, other named mentors and at least one non-mentor referee. (*The typical applicant will have a primary mentor and two referees.*) Instructions for applicants and responsible officials can be downloaded [HERE](#). Instructions for mentors and referees can be downloaded [HERE](#). The recommendations must be completed in the Autism Speaks Science Grants System (**no uploads**) and will address the following information about the candidate:
 - i. commitment to a career focusing on CAPD-oriented research
 - ii. potential for conducting research
 - iii. adequacy of scientific and academic background with specific reference to the candidate's academic and research endeavors, including any publications, to date
 - iv. evidence of originality
 - v. specific areas of further research training that would benefit the candidate
 - vi. any additional related comments that the referee may wish to provide

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

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; is not responsive to its research training goals; and/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.

Notification 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.

Fellowship 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-US 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:** 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 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:

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Application Development:

Donna Murray PhD, Vice President, Clinical Programs: donna.murray@autismspeaks.org

APPENDIX: Responsible Conduct of Research Plan for Fellowship Applicants

Outline all previous, current, and future instruction. 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:

- a. Conflict of interest – personal, professional, and financial
- b. Policies regarding human subjects, live vertebrate animal subjects in research and safe laboratory practices
- c. Sponsor/fellow responsibilities and relationships
- d. Collaborative research including collaborations with industry
- e. Peer review, including confidentiality and disclosure of participation by anyone not directly assigned to the materials under review
- f. Data acquisition and laboratory tools; data management, sharing and ownership
- g. Research misconduct and policies for handling misconduct
- h. Responsible authorship and publication, with topics including fabrication, falsification and plagiarism
- i. 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, 3 pages max, Arial 11 font, 1 inch margins, single spaced is acceptable.