

# Autism Speaks Predoctoral Fellowship Program 2022 Request for Applications

#### **Deadlines:**

Letter of Intent due on or before: February 1, 2022, 8:00 p.m. (U.S. Eastern Time) Letter of Intent decisions: mid-February 2022 Recommendations (see page 6) due on or before: April 5, 2022 by 8:00 pm (ET) Application due on or before: April 12, 2022 by 8:00 pm (ET)

### Other Important Dates (subject to change):

Peer review panels: Spring/Summer 2022 Notification: August 2022 Earliest Grant start date: November 2022

Autism Speaks is dedicated to promoting solutions, across the spectrum and throughout the life span, for the needs of individuals with autism and their families. We do this through advocacy and support; increasing understanding and acceptance of autism spectrum disorder; and advancing research into causes and better interventions for autism spectrum disorder and related conditions. We empower people with autism and their families with resources, online tools and information covering the life span.

Autism Speaks invites applications from predoctoral students interested in pursuing careers in autism research. The fellows will work directly with mentors who are leading scientists in autism-related research. This program supports the growth of a promising cadre of early career scientists who will make autism research their chosen field.

The primary purpose of the predoctoral fellowship is to provide highly qualified candidates with exceptional research training opportunities broadly related to the study of autism spectrum disorder (ASD). Areas of research Autism Speaks is most interested in funding include:

- Epigenetics
- Pre-clinical intervention studies, including gene and RNA editing
- Mental health comorbidities with an emphasis on interventions
- Biomarkers and objective measurement of autism and related domains
- Adult transition and lifespan development
- Cognitively disabled and/or non- or minimally verbal
- \* Innovative implementation of technology to enhance reach and impact of services with an emphasis on diagnosis and intervention in low resource settings, especially among ethnic minority, rural and other marginalized populations
- Inclusion of individuals from low-resource communities (For research that involves human subjects, Autism Speaks will prioritize study designs that include and better reflect the diversity of the community that we serve.)

\*Timely access to effective services contributes to wellbeing and better outcomes for all individuals and families affected by autism. Yet, recent studies have shown location, SES and other social determinants continue to limit access to needed support for many individuals and their families. Like other health disparities, those associated with autism are only likely to increase during the pandemic. Autism Speaks is interested in innovative implementation of technologies to address these barriers and enhance the reach and impact of ascertainment and intervention services, especially among ethnic minority, rural and other marginalized populations.

# Awards

The Autism Speaks Predoctoral Fellowship Awards will be granted to qualified predoctoral students. The **two-year fellowship** includes an annual **\$37,000** award that combines a stipend of **\$26,000 plus a \$11,000 annual allowance** for fringe benefits, research costs and supplies, professional travel and/or tuition reimbursement. Indirect costs are not allowed. Acceptance of any other award or grant that supplements research training expenses or the stipend requires approval that will be granted in rare and exceptional cases.

# **Eligibility and Roles**

**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 their program. The selected predoctoral fellow must spend at least 80% of his/her professional time engaged exclusively in their Autism Speaks' autism research-related activities for the duration of the award and cannot simultaneously hold another fellowship award during the support period. International applications are encouraged.

**Mentors:** Prior to application, predoctoral candidates must have an identified mentor for their 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.

**Resubmissions:** Candidates are allowed one resubmission of a previously denied Autism Speaks application (within two years). Resubmissions must meet the following requirements to be considered for review:

- 1. The LOI must indicate that the application is a resubmission and enter the prior ID# in the field provided. Also, it must include an Introduction describing how the resubmitted application will address the comments from the previous review, in the field provided (2,500 characters, spaces included).
- 2. If the LOI is approved, the Introduction can be expanded (8,000 characters, spaces included).
- 3. The new application research plan and other changed documents should indicate all substantive text changes. Changes should be easily identifiable using brackets, indents or a distinguishable font. Do not underline or shade the changes. If significant portions of the original application research plan or other documents are deleted, the deletion should be explained in the Introduction. The application should also describe additional work completed since the original submission.

# Autism Speaks limits the application procedure to only one predoctoral fellowship submission from <u>any fellow or any mentor</u> per LOI/application process and applies to the LOI as well as the full application.

# **General Information**

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

Please Note:

- 1. The Fellowship candidate must be the applicant. If you are new to our system, register with your <u>institutional email</u> address. Otherwise log in to your previously established account. We recommend using the following browsers: Chrome, Firefox, Safari or IE 11 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. All users must utilize Google Authenticator in order to log in to the system. There are on screen instructions as well as this <u>guide</u>.

- 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. Fellows should use the regular NIH biosketch rather than the fellow biosketch.
- 7. Applications or LOIs 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 regard to late submissions will be final. <u>It is the applicant's responsibility to plan around holidays or any special circumstances at their institution.</u>
- 8. It is the applicant's responsibility to contact their Office of Sponsored Projects or Research Administration (or the equivalent) to identify the Responsible Official (RO) for this application. The RO 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 but the RO must be named and will be included on notifications. Full applications can only be submitted by the RO.
- 9. There are no geographic restrictions on these applications. International applicants are encouraged.
- 10. Please note that there will be lay advocates reading submitted applications.

### 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 Fellowships 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**: Enter up to 1,500 characters, spaces included, to describe the project goal(s) and/or hypothesis, specific aims, research methods, expected results and significance/relevance to Autism Speaks' targeted research areas as stated above.
  - c. If the application is a resubmission, select "Yes" and the previous Autism Speaks ID number from the dropdown list of eligible IDs. If there are no available IDs, then you cannot resubmit. The Introduction should explain how the resubmission will address the reviewers' concerns or issues from the original application. (2,500 characters, spaces included).
  - d. **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.
  - e. **Responsible Official**: Choose the Responsible Official (RO) (Research Administrator) from the PI's institution. You must have an institutional email to add a new person. *A mentor cannot also serve as an RO.*
  - f. **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.
  - g. Note: All this information will be available for review and editing at the application stage.
- 2. LOI form includes:
  - a. **Expected Graduation –** As stated in Eligibility above, candidates should have two or more years remaining.
  - b. **Priority –** Select the priority which this application is addressing (from list on page 1).
  - c. **Impact** Briefly explain how the work will impact the lives of those living with autism and/or their families.
  - d. **Training plan summary**: Short summary (up to 4,000 characters, spaces included) of the training plan and how it will contribute to the fellow's career development. Include training activities outside of the research (courses, rotations, conferences, etc.).
  - e. **Fellow biosketch:** NIH format not to exceed 5 pages. Biosketches should only contain published or in-press manuscripts.

- f. Primary mentor biosketch: NIH format not to exceed 5 pages.
- g. 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. All LOI decisions are final and no comments will be available.

### Complete the full application.

- ORCID profiles Autism Speaks policy requires all applicants and mentors to obtain ORCID profiles. <u>Link to Help document</u>.
  - 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. Having just an ORCID profile is insufficient. (See the <u>Help</u> <u>document</u>). Applicants cannot do this for the mentors; each mentor must log in and complete his or her own connection. <u>An application will not be reviewed until this is</u> <u>complete</u>. All mentors named on an application will receive an email with instructions however the applicant is encouraged to follow up with each individual. (*This is optional but encouraged for consultants and non-mentor referees*.)
- 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 #17 below.
- 3. All of the remaining items will be found on the Application Form Page.
- 4. Expected PhD graduation
- 5. **Priority –** Select the priority which this application is addressing (from list on page 1).
- 6. **Impact** Briefly explain how the work will impact the lives of those living with autism and/or their families. (Repeat or expand the answer from the LOI).
- 7. Research Plan: Not to exceed 6 pages, uploaded document. Include:
  - a. Specific aims, background and significance/relevance to autism.
  - 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.
  - d. For research that involves human subjects, Autism Speaks will prioritize study designs that include and better reflect the diversity of the community that we serve.
- 8. **Timeline:** Up to 2 pages. Create a timeline showing the expected milestones for the achievement of the aims. Note: Word, Excel, PDF, or picture are acceptable.
- 9. **Statistical Analysis Plan** upload 1 page explaining the statistical analysis plan, If there will be none, upload a memo to that effect.
- 10. **Individualized Development Plan (IDP):** Not to exceed 3 pages, uploaded document. There is no template just cover the information explained here. The Predoctoral Fellowship program is dedicated to encouraging promising scientists to join the autism research community as productive researchers. The mentor's role is to foster the development of the fellow's overall knowledge of autism 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 that build on the fellow's pervious experiences while expanding their knowledge and experience in autism. 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

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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 autism. Both mentor and fellow should sign this document before uploading.

- 11. **Responsible Conduct of Research Plan**: Not to exceed 3 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.
- 12. **Bibliography** with complete literature citations including titles and all authors. Uploaded document.
- 13. **Budget:** The applicant must complete the online budget table showing how the research allowance will be spent. Indirect costs are not allowed. Stipends cannot be reallocated to other parts of the budget nor can other parts of the budget be reallocated to the stipend. Allowable categories are
  - a. Tuition Reimbursement
  - b. Fringe benefits
  - c. Research Supplies
  - d. Travel
  - e. Animal/Human Subjects Costs
  - f. Mentor Support Up to \$500 of the Research Allowance can be allocated for primary mentor's salary support or travel. The explanation of the plans should be included in the Budget Justification.
  - g. Other (must be explained in the budget justification).
- 14. **Budget Justification:** Provide a detailed justification for each item on the budget. Include calculation(s) used. Uploaded document.
- 15. Explain Inclusion of Human Subjects and/or Vertebrate Animals: Up to 5,000 characters, spaces included. Applications that use human subjects or vertebrate animals must address issues of protections, addressing the applicable issues listed below. 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 is minimized. Please include the method of euthanasia and the reasons for its selection.
- c. Please state if no human subjects or vertebrate animals will be used in the project.

- 16. **Consent forms** (if applicable): If this project will be working with human subjects, upload the consent forms that will be used with the participants. Please note if they have not yet been approved by your IRB.
- 17. Letters of Collaboration (optional): Up to two, one-page letters of collaboration may be submitted describing a collaborative arrangement. Combine multiple letters for upload.
- 18. Biographical sketches of 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 encouraged. 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.
- 19. **Publications:** Upload up to two publications that support the project. These do not have to be authored by the fellow or the mentor. The files MUST NOT be locked or secured in any way.
- 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.
- 21. 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 <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 (<u>no uploads</u>) and will address the following information about the candidate:
  - i. Commitment to a career focusing on autism-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 <u>Autism Speaks Science Grants System</u>. 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.

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 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 will be posted on the Autism Speaks website and be included in the <u>Grants Search</u>.

# **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 will be paid half of Year 1 up front and further 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.

#### **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 lay partners in the broader autism 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.*)

Questions? Contact Joan New, MBA, Grants Manager, 609-228-7313, jnew@autismspeaks.org

# **APPENDIX: Responsible Conduct of Research Plan**

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 and 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.