



**Request for Applications:
Pilot Studies of Profound Autism
and/or Severe, Intense and Dangerous Behaviors**

**RFA Released: August 1, 2024
Applications Due: October 18, 2024, 5PM Eastern
Anticipated project start date: April 1, 2025**

Introduction

The *Lancet* Commission on the Future of Care and Clinical Research in Autism introduced the term “profound autism” and encouraged its use to describe autistic people who are at least 8 years old, minimally verbal or nonverbal, have IQ below 50, are not able to advocate for themselves, and will likely require 24-hour access to an adult who can care for them for the rest of their lives.

Past research has established that individuals with autism exhibit a wide range of abilities and disabilities and that those with challenging or problematic behavior, minimal verbal ability, and/or intellectual disability are demonstrably [underrepresented in research](#). Their exclusion prevents the generalizability of research discoveries and impedes understanding of the supports and interventions they require to live fulfilling lives. There is an immediate need for research to identify the specific and unique needs of individuals with profound autism.

While the *Lancet* definition does not specify the presence of severe, intense and dangerous behaviors, this RFA also includes research on severe and challenging

behaviors including self-injury, aggression, PICA, wandering and irritability, which are prevalent in those with profound autism but not part of the *Lancet* definition.

This RFA specifically calls for:

- 1) pilot studies to identify or characterize the underlying biological mechanisms of profound autism (including model systems);
- 2) examination of the preliminary efficacy of a behavioral or pharmacological treatment for core or co-morbid symptoms of profound autism or severe, intense and dangerous behaviors;
- 3) projects which address challenges in recruitment, retention or data collection in individuals with profound autism.

For the purposes of this RFA, profound autism is defined as minimally or non-verbal, and/or IQ less than 50, and requiring the need for 24/7 care to ensure safety. Individuals with Profound Autism may or may not exhibit severe and dangerous behaviors. Research on severe and dangerous behaviors does not need to be exclusive to those with Profound Autism.

Preference will be given to those studies that include a control arm, or a group of those with non-profound autism.

Requirements:

The award may be used to cover supplies or salary support and fringe for staff, including post-doctoral fellows, tenured or tenure-track faculty or other percent effort. It also may be used to cover small amounts of consulting costs.

This year, the mechanism may also be used to support a one-year, mentor-based pre-doctoral fellowship focused on the topics described above. If the pre-doctoral applicant is the PI, the application must include both a training plan and a letter of recommendation from someone other than the mentor named on their application.

All investigators must include a letter of support from an advocacy organization involved in profound autism. The advocacy organization is expected to act in an advisory capacity, help with recruitment, and support dissemination. Examples of organizations that have written strong letters in the past include the Profound Autism Alliance and the National Council on Severe Autism. Patient Advocacy Groups (PAGs) that represent families with idiopathic autism or with rare genetic syndromes that result in a high prevalence of neurodevelopmental disorders, including autism are also good choices. Many of these groups are represented in the Alliance for Genetic Etiologies in Neurodevelopmental Disorders and Autism ([AGENDA](#)). Collaborations and partnerships with local organizations or other autism service organizations are also very welcome. Examples include the [Bancroft School](#) and [The Center for Discovery](#). These are examples; this is not an exhaustive list.

Awards

The Autism Science Foundation will award multiple pilot grants determined by available financial resources. The term of the award will be one year and the grant will support up to \$35,000.

This award cannot be used to cover tuition payments. No portion of these funds shall be used to cover indirect university costs.

Eligibility and Requirements of the Project:

Applicants for this award must be either enrolled in a pre-doctoral training program, or hold an M.D., Ph.D., EdD, or ScD and currently hold a position at a university or institution, or an organization with 501c3 status. U.S. citizens may be enrolled in universities inside or outside of the United States. Non-U.S. citizens may be enrolled in universities inside or outside of the U.S. Post-doctoral fellows may receive stipend support for a percentage of their effort spent on the project.

Proposal Preparation

Proposals must be written using 12-point Arial font with margins of 0.5 inches or greater with line spacing at 1.5. The applicant's last name must appear in the header on every page of the proposal. Items 1 -5 should be assembled into a single .pdf document.

1. Title Page

The title page should include the applicant's name and full contact information (including a permanent, non-university affiliated email address), ORCID ID, race and ethnicity, project title, and name of the sponsoring institution. There may be multiple co-PIs on the project, but there needs to be one lead PI to whom the funding will be directed and who takes administrative responsibility for the project. Pre-doctoral applicants must indicate that it is a pre-doctoral fellowship application and include a mentor name, affiliation and email addresses on the cover page.

2. Proposal Abstract (Max. 500 words) and Lay Abstract (Max. 250 words)

The proposal abstract should indicate the goals and objectives of the project and clearly state the value of the work toward improving the lives of people with profound autism or severe and challenging behaviors.

The lay abstract must be intelligible to a knowledgeable layperson or non-expert. It should not include jargon and should clearly and succinctly state the goals of the project and the expected impact on people with autism and their families. It should not regurgitate the scientific abstract. Basic science projects should focus on the discovery value of the work if there is no immediate benefit.

3. Research and Analytic Plan (Maximum 7 pages)

The top of this section should state "Research and Analytic Plan" in bold underline.

Use 12 point font with 1.5 spacing and margins of at least 0.5 inches.

The plan should describe the specific project, including the rationale and background, relevance to understanding those with profound autism or severe and challenging behaviors, any preliminary data, specific aims, methodology, participant

characterization and recruitment (if applicable), expected results and how they will be shared, and the timeline for completion. Please note that for animal studies, ASF strongly encourages applicants to [follow this guidance](#).

We recommend that proposals include a statement of how the application is responsive to the RFA and needs of those with profound autism. Basic science projects should focus on the discovery value of the work if there is no immediate benefit to people. While there are various interpretations of the term “profound autism” we require use of the Lancet definition in these applications. Other groups can be included, but will be defined as non-profound autism.

4. Bibliography - (2 pages max)

The top of the section should state “References” or “Bibliography” in bold underline.

Use 12 point font with 1.5 spacing and margins of at least 0.5 inches.

We recommend numbered references to save space in the Research and Analytic Plan section.

Include complete literature citations, including titles and all authors.

5. Budget, Timeline and Budget Justification (1 page max)

The top of the section should state “Budget, Timeline and Budget Justification” in bold underline.

Use 12 point font with 1.5 spacing and margins of at least 0.5 inches.

The budget should include a breakdown of all the expenses, where the funding will go and to whom/what for the full funding amount. Each item should include a justification. A table listing the type of expense, the justification, and the amount is sufficient. For those holding positions at institutions (including post-doctoral fellowships) funding can be used to support salaries and fringe benefits, but should

not exceed \$20,000 total. For pre-doctoral fellows, the entire budget can support salary and fringe benefits.

6. Biosketch (es): In a separate document, provide a biosketch for the PI and anyone receiving salary support, at all career levels. For pre-doctoral applicants, include a biosketch of the mentor.

7. Support letter from Patient Advocacy Group

A letter from a Patient Advocacy Group, support group, or organization that works directly with families is required. This letter should highlight the role that the organization will play in the project and the specific activities they will undertake to help support the research. They should also describe any unique expertise they have that will help ensure the project delivers results. This letter should be included in the application packet, not sent directly to ASF. Basic science projects have received outstanding letters from patient advocacy groups in the past so don't let this discourage application.

7. Letters of Recommendation and Training plan (Pre-doctoral fellows only)

If the PI is a pre-doctoral fellow, a letter of recommendation is required. It should come from someone who is not the mentor or advisor, but who is familiar with the applicant and addresses his/her education, research training and experience, and professional career goals in autism research.

Mentors should also indicate current funding source(s), total award amounts, award durations (inclusive dates), project titles and clearly explain the extent to which currently funded research projects will overlap, complement and/or contribute to the training of the Awardee. Mentors may also choose to list recent (last 3 years) as well as pending grant support relevant to autism research.

The letter of recommendation should be submitted separately and sent directly to ASF (not included in the application packet) by the recommender as a PDF document on official letterhead. *Letters received as a word or google document will not be accepted.*

The letter should be submitted directly from the recommender to ASF by email to grants@autismsciencefoundation.org.

Please ask your recommender to use the subject line:

Applicant Last Name/Institution/Letter

Type Example: Martin/Tulane/Letter of Recommendation

If the applicant is NOT a predoctoral fellow, no letter of recommendation is necessary.

The Training Plan highly impacts the review and award decisions. It should be ***prepared by the mentor in collaboration with the trainee***. The mentor should provide a thorough description of a training program that includes a clear logical plan of professional development for a future career in autism research specific to the applicant, as well as a comprehensive summary of the mentor's autism research and experience mentoring other students and postdocs. The training plan should include exposure to both clinical and basic sciences, and should take advantage of opportunities outside the university, including community based training. If an advisor is included in the project, his/her expertise and role on the career development of the applicant in autism research should be described. Special attention should be given to the interaction between the advisor and the trainee if the advisor is at a different organization or research institution. The training plan should also utilize the relevant research and educational resources of the institution, including the research environment and the availability and quality of needed research resources. The training plan should be specific to autism, not just a training plan in science. In past grant cycles, highly qualified applicants have been rejected due to mentors submitting inadequate, overly generic training plans. It should also utilize the relevant research and educational resources of the institution, including the research environment and the availability and quality of needed research resources.

Mentors should also indicate current funding source(s), total award amounts, award durations (inclusive dates), project titles and clearly explain the extent to which currently funded research projects will overlap, complement and/or contribute to the training of the Awardee. Mentors may also choose to list recent (last 3 years) as well as pending grant support relevant to autism research.

If the applicant is NOT a predoctoral fellow, no training plan is necessary.

Revisions:

Proposals reviewed but unfunded during the last cycle may be resubmitted for reconsideration. (If submitted prior to our 2024 funding cycle, the proposal would be considered a new submission.) In addition to the proposal, the applicant should provide a one page, single-spaced letter addressing the changes made in response to the reviewers' comments. The one-page, single-spaced letter will not be included in the proposal page limit; it should only contain information relevant to the reviewers' previous comments and suggestions. The revised proposal should be submitted without track changes or other editing notation.

Submission of Proposals

Proposals should be submitted by email as one .pdf document with the subject line: Last Name/Institution/ProfoundAutismGrant to grants@autismsciencefoundation.org.

Example: Martin/Tulane/ProfoundAutismGrant

Successful electronic submission will be confirmed by email notification to the sender.

Applications are due **October 18, 2024** by 5:00PM ET. This deadline applies to both the proposal and all applicable letter(s). It is your responsibility to inform letter writers of this deadline. Any proposals or letters received after this deadline will not be reviewed.

It is the applicant's responsibility to ensure that the proposal complies with the conditions prescribed in the RFA. Autism Science Foundation reserves the right to return without review any proposal found not to comply with the conditions prescribed in the RFA, or any proposal that is not responsive to its research goals or exceeds its funding limits or available resources, at any time during the application and review process.

The Autism Science Foundation reserves the right to make changes to this RFA at any time. Changes will be posted on the website. We advise applicants to check this link frequently:

<https://autismsciencefoundation.org/apply-for-a-profound-autism-pilot-grant/>

Review Process and Evaluation Criteria

Proposals will be reviewed by members of the Autism Science Foundation's Scientific Advisory Board, as well as by active and experienced investigators recruited from the scientific community for their expertise in the research areas of the proposals. Proposals may also be reviewed by a panel of experienced laypersons (parents, individuals with autism, other advocates) who will provide input to the Scientific Advisory Board.

Additional questions about proposal submission, proposal content and review, or applicant eligibility should be addressed to Dr. Alycia Halladay, Autism Science Foundation's Chief Science Officer, at ahalladay@autismsciencefoundation.org.

Award Notification and Start Dates

Award notifications will be made in February 2025. We expect grants offices to sign off on contracts and projects to begin no later than April 1, 2025. ***We highly suggest determining if the approval of an IRB or IACUC amendment is possible between notification and April 1st. We will not extend the start date due to IRB delays.*** In addition, if the grants office has significant delays in signing off on the contract, we have the right to rescind the offer. If your grants office needs a sample template to review one can be found here:

<https://autismsciencefoundation.org/grantee-resources/>

Payment of Awards

Upon notification of award, we will require a copy of the underlying project's IRB approval letter. Upon receipt of the IRB letter by ASF, we will issue a contract to the investigator's sponsoring institution and make a single payment of the full amount. Please note, sponsoring institutions must accept the contract as is, or with only minor revisions. A sample contract is available for your grants office to review in advance to ensure the institution will be able to agree to the terms. The sample contract can be found at

<https://autismsciencefoundation.org/wp-content/uploads/2022/02/Sample-ASF-Grant-Contract.pdf>.

Awardees must submit a brief written report to the Autism Science Foundation at the conclusion of the award, documenting the status of the research funded and detailing the use of funds. The format for this form will be provided by ASF. All forms can be found at <https://autismsciencefoundation.org/grantee-resources/>

Questions?

A question-and-answer session will be held on September 11th at 12 p.m. ET to review the goals of this RFA. It will include tips on writing a strong application.

Please register here:

<https://us06web.zoom.us/meeting/register/tZcrcOigqDkuHNfp61crouebaeVwjrln2iyX>

Questions about proposal submission, proposal content and review, or applicant eligibility should be addressed to Dr. Alycia Halladay, Chief Science Officer, Autism Science Foundation. (ahalladay@autismsciencefoundation.org)

